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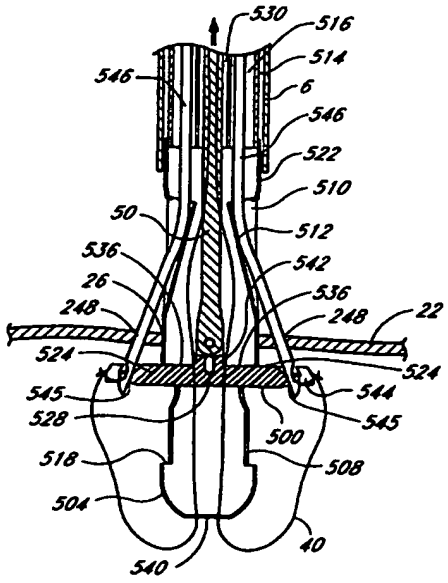
(54) Title: SUTURING DEVICE FOR SEALING AN OPENING IN A BLOOD VESSEL

(57) Abstract

A suturing device (520) allows a physician to remotely seal an incision (26) in a blood vessel (16) or other biological tissue. The device (520) comprises an elongated tubular body (514, 515) having a distal portion (515, 522) which is adapted to be inserted percutaneously through the incision (26) and into the blood vessel (16). The distal portion (515, 522) has at least first and second retractable arms (524, 525, 525', 630, 630', 660, 662) which extend from the distal portion (515, 522) of the body (514, 515) and releasably hold a suture (40) within the blood vessel (16). First and second retractable needles (546, 650), each of which is configured to catch the suture (40) from a respective arm (524, 525, 525', 630, 630', 660, 662), are provided along the body (514, 515) proximal to retractable arms (524, 525, 525', 630, 630', 660, 662). The arms (524, 525, 525', 630, 630', 660, 662) and the needles (546, 650) are remotely movable by the physician using a handle (550, 600, 700) or other control mechanism provided at a distal portion of the device (520). In operation, the arms (524, 525, 525', 630, 630', 660, 662) are initially deployed within the blood vessel (16) to hold the ends of the suture (40) beyond the circumference of the tubular body (514, 515). The needles (546, 650) are then deployed from and then retracted into the body (514, 515), during which time the needles (546, 650) pierce the wall (22) of the vessel (16) on substantially opposite sides of the incision (26), release the suture end from the retractable arms (524, 525, 525', 630, 630', 660, 662), and pull the suture (40) through the vessel wall (22). The device (520) is particularly useful for closing and incision (22) in an artery following a catheterization procedure. In one embodiment, the catheter sheath introducer (6) used to perform the catheterization procedure is left in place during the suturing procedure.



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SUTURING DEVICE FOR SEALING AN OPENING IN A BLOOD VESSEL

Background of the Invention

Field of the Invention

The present invention relates to medical suturing devices. More particularly, the present invention relates to suturing devices for closing an opening in an arterial or other biological tissue wall that is not directly accessible to the physician.

Brief Description of the Related Art

Physicians frequently use sutures to close cuts, punctures, incisions and other openings in various biological tissue, such as blood vessels, of the human body.

In an arterial catheterization procedure, a relatively small percutaneous incision is made in the femoral or other artery. A catheter is inserted through the incision and directed along an arterial path to a target area, such as the heart, to perform one or more procedures, such as an angioplasty or angiogram. These procedures are designed to be relatively quick 'outpatient' procedures.

Upon completion of the catheterization procedure, the physician typically creates a 'thrombus patch' by applying direct pressure to the patient's thigh to make the blood around the incision clot. Because the femoral artery must not be completely blocked (occluded) by the applied pressure, the physician commonly applies direct pressure by hand for the first twenty minutes after the procedure. During this time, the physician can feel the pulse to assure the artery is not occluded. Afterwards, the physician usually turns the procedure over to an assistant who applies direct pressure using sandbags, clamps or other devices. A significant problem with this approach is that it is frequently necessary to apply the pressure for an extended period of time, such as twenty-four hours or longer.

Another problem with the thrombus patch method is that the high blood pressure in the artery can cause the thrombus patch to rupture or burst while direct pressure is being applied to the thigh or after direct pressure is removed. This requires the whole process to be restarted. If the patch ruptures and is not restored, the patient may bleed to death. Because thrombus patches frequently burst, the patient frequently must remain in the hospital or catheterization lab overnight for observation. Thus, these 'out-patient' procedures become 'in-patient' procedures, simply because a thrombus patch it is difficult to create. Staying in the hospital increases patient discomfort and hospital expenses, which are often disproportionate to the actual medical procedure performed.

Furthermore, if a thrombus patch cannot be formed, the physician may need to anesthetize the patient, occlude blood flow to the artery, make a large incision in the thigh to allow conventional suturing with a needle, suture the artery with conventional means, restore blood flow to the artery, and suture the incision in the thigh. This results in additional discomfort and expenses for the patient.

While the above problems could potentially be avoided by suturing the blood vessel immediately following the catheterization procedure, the size and location of the artery make suturing difficult. Specifically, the opening in the thigh is typically too small and too deep to provide enough working space for suturing the artery using

conventional methods. Thus, in order to suture the vessel according to conventional methods, the opening in the thigh would have to be significantly enlarged, potentially exposing the patient to additional pain, scarring, and health risks.

Summary of the Invention

The present invention addresses the above problems by providing a suturing device and method for suturing an opening in a biological tissue wall, such as an organ or blood vessel. The device is particularly well suited to suture an opening made in an artery, such as the femoral artery, following a catheterization procedure. The device eliminates the need to apply pressure to a patient's thigh for an extended period of time, and eliminates many of the complications and costs associated with the creation of a thrombus patch.

In a preferred embodiment, the device comprises an elongated tubular body having a distal portion which is adapted to be inserted percutaneously through an initial incision and into the blood vessel. The distal portion has a pair of retractable arms which can extend from the distal portion of the elongated body and releasably hold a suture within the blood vessel. The arms retract into and extend out from respective openings on sides of the elongated tubular body.

First and second retractable needles, each of which is configured to catch the suture or a looped end of the suture from a respective retractable arm, are provided along the elongated body proximal to the retractable arms. The arms and the needles are remotely movable by the physician using a handle or other control mechanism provided at a distal portion of the device. The needles extend distally and outwardly from the elongated body (preferably by flexing outward during deployment) to capture the suture.

In operation, following a catheterization procedure in which a standard catheter sheath introducer (CSI) is used to introduce a catheter into a blood vessel, the distal portion of the elongated body is introduced into the blood vessel through the CSI. The CSI may advantageously be left substantially in the inserted position during the suturing procedure. During insertion, the retractable arms are maintained in their retracted position. Once inside the blood vessel, the arms are deployed to hold the ends of the suture beyond the circumference of the elongated tubular body. Using a control handle, the needles are then deployed from and then retracted into the elongated body, during which time the needles pierce the vessel wall on substantially opposite sides of the incision, release and capture the suture ends from the retractable arms, and pull the ends of the suture through the vessel wall. The arms are then moved to their retracted position, and the device is withdrawn from the blood vessel and the patient's body with the ends of the suture. A knot or suture clip may then be advanced to the incision site to close the incision.

In accordance with the invention, there is thus provided a suturing device for remotely sealing an incision in a wall of a blood vessel or other biological structure. The suturing device comprises an elongated body having a distal portion which is adapted to be inserted through the incision and into the blood vessel. The distal portion has an outer wall with first and second apertures formed therein. The elongated body further comprises first and second needle ports positioned proximal to the distal portion such that the needle ports remain outside the blood vessel when the distal portion is positioned within the blood vessel. The device further comprises first and second

arms which retract into and extend out from the first and second apertures, respectively, and which releasably hold a suture. The arms are remotely movable to a deployed position in which the arms extend outward from the body to hold the suture away from the body. First and second needles extend from the first and second needle ports, respectively, to capture the suture. The needles are remotely movable between a retracted position in which the needles are housed within the body, and an extended position in which the needles extend distally from the needle ports and outwardly from the body. Movement of the needles from the retracted position to the extended position, and back to the retracted position, with the arms deployed within the blood vessel and holding the suture, causes the needles to pierce the blood vessel, release the suture from the arms, and withdraw a portion of the suture from the blood vessel.

The distal section of the elongated body, including the needles and the needle ports, is preferably configured to be percutaneously introduced into a patient through a standard CSI used to perform a catheterization procedure, such that the needles may be extended and retracted to capture and withdraw the suture without removing the CSI from the patient. A proximal section of the elongated body preferably includes a marker on an outer surface, the marker indicating a longitudinal position to which the CSI may be partially withdrawn to expose the needle ports.

The needles preferably have a substantially straight configuration when in the retracted position, and bend outward away from the body when in the extended position. The needle ports preferably include needle guides which apply an outward force to the needles to cause the needles to bend outward. In one embodiment, each needle includes a notch formed therein for capturing a loop in the suture. In another embodiment, each needle includes groove formed circumferentially therein, the groove being configured to engage a loop or fitting at an end of the suture.

The first and second arms are preferably interconnected by a flexible, resilient hinge which holds the arms in a partially open position when the hinge is in a relaxed state. The flexible hinge is preferably coupled to an actuator shaft which extends within a lumen of the body, such that application of a proximal force to the actuator shaft causes the arms to move from the partially open position to the deployed position, and such that application of a distal force to the actuator shaft causes the arms to move from the partially open position to a retracted position. The outer surfaces of the first and second arms are preferably flush with an outer surface of the body, and the arms substantially parallel to the body, when the arms are retracted within the body. The first and second arms preferably extend radially outward from the body at an angle of approximately 90 degrees when in the deployed position. The arms are preferably spaced proximally from a distal tip of the body, so that the arms are inhibited from contacting a wall of the blood vessel opposite the incision during deployment.

The distal portion of the body preferably includes at least one blood port which is fluidly coupled to a lumen within the elongated body. The lumen extends to a proximal portion of the elongated body to allow a physician to determine whether the distal portion is in the blood vessel. The lumen may be coupled to a pressure sensor that provides a visual indication of whether the distal portion is in the blood vessel.

Brief Description of the Drawings

Figure 1A illustrates a distal section of a suturing device in accordance with the present invention in an exemplary use environment, with the device shown on cut-away form .

Figure 1B is a cross-sectional view of the device of Figure 1A.

Figure 2 is a cross-sectional view which illustrates the construction of the device of Figure 1A in accordance with one embodiment of the invention, wherein the distal end of the device is shown inserted through a blood vessel wall.

Figure 3 is a cross-sectional view of the device of Figure 2 with the suture clasp member partially deployed.

Figure 4A is a perspective, cut-away view of the device of Figure 2, showing a suture clasp member, an actuator and a hollow elongated body.

Figure 4B is an exploded view of the suture clasp member, pivot pin and actuator of Figure 4A.

Figure 4C is a perspective view of a two-piece suture clasp member according to another embodiment of the invention.

Figure 4D is a cross-sectional view of the two-piece suture clasp member of Figure 4C and a spreader within a suture introducer head.

Figure 5 is a perspective view of the suture introducer head and suture clasp member of Figure 2.

Figure 6 is perspective view of the device of Figure 2 with the suture clasp member partially deployed and holding a suture.

Figure 7 is a perspective cut-away view of the device of Figure 2.

Figure 8 is cross-sectional view of the device of Figure 2 with the suture clasp arms fully deployed and holding a suture within a blood vessel.

Figure 9 is a cross-sectional view of another embodiment of the Figure 1A device.

Figure 10 is a cross-sectional view of a handle of the device of Figure 1A according to one embodiment of the invention.

Figure 11 is a perspective view of the handle of Figure 10.

Figure 12 is a cross-sectional view of a handle according to another embodiment of the invention.

Figure 13A is a perspective view which illustrates another embodiment of the Figure 1A device.

Figure 13B is a cross-sectional view of the device of Figure 13A.

Figure 14A-14B are perspective views of a two-piece configuration of the suture clasp member of Figure 13A.

Figure 15 is a perspective view of the device of Figure 13A with the suture clasp arms partially deployed.

Figure 16 is a perspective view of the device of Figure 13A with the suture clasp arms fully deployed.

Figure 17 is a perspective view of the device of Figure 13A with the suture clasp arms fully deployed and needles engaging the suture clasp member.

Figure 18 is a perspective view of the Figure 1A device with the handle of Figure 10.

Figures 19-20 are perspective views of a four-arm suture clasp assembly according to another embodiment of the invention.

Figure 21 is an exploded view of a handle according to another embodiment of the invention.

Figure 22 is a perspective view of the handle of Figure 21.

Detailed Description of the Preferred Embodiments

The present invention provides a suturing device for suturing biological tissue. Various embodiments of the suturing device are described below. In the disclosed embodiments, the device is adapted to be used to seal an incision in a blood vessel. As will be recognized by those skilled in the art, the disclosed design can also be used to seal incisions in other types of biological structures, such as a patent ductus arteriosus, a patent foramen ovale, a heart defect, or a puncture wound.

Figures 1A-1B illustrate the suturing device 520 in accordance with a preferred embodiment of the present invention in an exemplary use environment. In Figures 1A-1B, the suturing device 520 is used to seal a blood vessel 16 following an interventional catheterization procedure, such as an angiogram. During the catheterization procedure, the physician makes an initial incision 20 in the upper thigh 12 of a patient 2. The physician then inserts a needle (not shown) into the incision 20. When blood bleeds back from the insertion, the physician knows the needle has pierced the femoral artery 16 through a blood vessel incision 26. The physician then inserts a guidewire (not shown) through the needle and into the artery 16. The physician may take the needle out and insert a plastic needle (not shown) over the guidewire once the guidewire is in place. The guidewire may then be taken out.

With this needle in place, the physician can insert a catheter sheath introducer (CSI) 6, also called an introducer sheath. This introducer sheath 6 is typically a single lumen catheter with a valve on its proximal end. The valve is used to prevent extraneous bleed back or to introduce medication into the patient's body. The vessel incision 26 provides access for medical instruments and probes to be inserted inside the arterial vessel 16. Instruments may be inserted into the artery 16 via the introducer sheath 6 to perform various medical procedures. For example, a catheter may be inserted through the CSI 6 and directed along an arterial path to a target area, such as the heart, to perform one or more percutaneous approach procedures, such as an angioplasty or angiogram.

After the medical procedure described above, the physician inserts a distal portion of the suturing device 520 into the biological tissue 14 through the CSI 6, as shown in Figures 1A-1B. The distal portion of the suturing device 520 passes through the CSI 6 and through the vessel incision 26 into the femoral artery 16. The device 520 is then used to place a suture through the wall 22 of the blood vessel 16 on either side of the vessel incision 26, so that the incision 26 can be efficiently and reliably sealed.

As described in detail below, the distal portion includes retractable arms 524 (seen in Figure 1B) which releasably hold the suture within the blood vessel 16. A set of flexible, retractable needles 546 (Figure 2) are used to pierce the blood vessel 16 on opposite sides of the incision 26, capture the ends of the suture from the arms, and withdraw the ends of the suture from the blood vessel 16. The arms and the needles can be remotely deployed and retracted by the physician as needed using a control handle, several embodiments of which are described below. Once the ends of the suture have been captured and withdrawn from the vessel 16, the device 520 is withdrawn from the CSI and the patient's thigh with the ends of the suture.

Figure 2 is a cross-sectional view of a preferred embodiment of the suturing device 520 of Figure 1A with the distal portion inserted through a blood vessel wall 22 via the incision 26. In Figure 2, the suturing device 520 comprises a suture introducer head 522, an elongated body 514, an actuating rod 50, an actuating rod lumen 530, a suture clasp member 500, a pivot pin 502, a pair of suture clasp arm apertures 508, a pair of flexible needles 546, a suture catch 38 on each needle 546, a pair of needle ports or apertures 510, a pair of needle insertion guides 512, a pair of needle housings or needle lumen 516, a suture 40, and an aperture 540 at the distal end of suture introducer head 522. The suture clasp member 500 comprises a pair of suture clasp arms 524, a pair of protrusions (suture clasp member stopper) 528, a hinge portion of the suture clasp member 542 and a pair of suture clasps 544. The device is illustrated in Figure 2 following insertion into blood vessel 16, but before deployment of the suture clasp arms 524. As illustrated in Figures 1B and 2 and described below, the CSI 6 is withdrawn from the blood vessel 16 to expose the needle ports 510 following insertion of the device, but remains inserted within the thigh. As illustrated in Figure 9, the device 520 may alternatively be constructed using a unitary body or housing 515, rather than using a separate suture introducer head 522.

The dimensions of the suturing device 520 may vary according to the suture site and the biological tissue intended to be sutured. In one configuration, which is used for suturing a femoral artery 16, the diameter of the suture head introducer 522 is about 0.105 inches, and the diameter of the hollow elongated body 514 is about 0.098 inches.

As shown in Figures 3 and 5-8, each needle port 510 corresponds to a respective suture clasp arm 524. Each needle port 510 includes a needle guiding portion 512 ("needle guide"), in the form of an outwardly curved groove or channel, which guides the corresponding needle 546 along a particular path. The needle guides 512 may be formed within the suture introducer head 522 (as shown in Figure 2) as part of a mold, or may be separate pieces (not shown) that are inserted into the suture introducer head 522 during manufacture.

As illustrated in Figure 8, as the needles are deployed distally to the extended position, the needle guides cause the needles 546 to bend outward so that they pierce the blood vessel on either side of the incision 26, and then engage the deployed suture clasp arms 524 to capture respective loops in the ends of the suture 40. Thereafter, the needles 546 are retracted to withdraw the ends of the suture 40 through the incisions 248 created by the needles.

Figure 7 shows a preferred configuration of the hollow elongated body 514 with five lumens. Two of the lumens 516 are used to house the needles 546 (Figure 2). Another lumen 530 is used to house the actuating rod 50. Another lumen 532 is used to hold the length of the suture 40 to prevent the suture 40 from becoming tangled. Alternatively, the suture 40 may be stored in the actuating rod lumen or in a hole drilled into the suture clasp arm 500.

The fifth lumen 534 is preferably used for 'bleed back,' which lets the physician determine whether the distal end 504 of the suture introducer head 522 is still positioned in the artery 16 after the physician partially removes the CSI 6. Bleed back is accomplished by the hole 540 (Figure 5) at the distal end 504 of the suture introducer head 522, the suture clasp arm apertures 508 and any other openings in the suture introducer head 522.

The direction of blood flow for bleed back is shown by the dashed arrows in Figures 2 and 9. If the distal end 504 of the introducer head 522 is still in the artery 16, the blood pressure measured by the blood coming up into the hole 540 will be much greater than if the distal end 504 is not in the artery 16. In one embodiment, the bleed back lumen 534 extends to a port (not shown) at a proximal portion of the device, and the physician can observe the blood pressure through bleed back lumen 534 by monitoring blood flow from the port. For example, the bleed back lumen may be attached to a balloon which inflates when the distal portion 504 of the suture introducer head 522 is within the blood vessel 16. In another embodiment, a pressure sensor is associated with the blood flow lumen 534 to provide the physician with a numeric reading. Alternatively, the fifth lumen 534 may be used to inject medication or for diagnostic purposes.

As shown in Figure 7, there are two thin stripes 538 (only one is shown in Figure 7) marked on the exterior of the elongated body 514. The stripes 538 indicate the rotational orientation of the suture introducer head by denoting circumferential locations of the two needles 546. The stripes 538 extend along a portion of the elongated body 514 which is outside the patient's flesh 14. The stripes 538 help the physician to align the needles 546 with the axis of the blood vessel 16, so that the needle incisions 248 (Figure 8) will be longitudinally aligned. As shown in Figure 2, the suture 40 preferably closes the artery vessel opening 26 transverse to the flow of blood. This is the most efficient direction to close the opening 26. Proper insertion of the needles 546 also reduces the risk of damage to the vessel walls 22, 506. Alternatively, in another configuration, there is only one stripe to denote the circumferential location of one of the two needles 546. The physician will know the circumferential location of the other needle 546 because the needles 546 are 180 degrees apart.

As illustrated in Figure 7, the exterior surface of the elongated body 514 includes a marker 539 which denotes the proximal position to which the CSI 6 should be partially withdrawn (after the distal portion of the suturing device 520 has been inserted into the blood vessel 16) to expose the needle apertures 510. The partial withdrawal of the CSI 6 is described below. The marker 539 is shown as a visual marker, but may additionally or alternatively be in the form of a ridge, groove, or other physical structure which interacts with a corresponding structure of the CSI 6 to allow the physician to position the CSI 6 using the sense of feel. For example, the CSI 6 and elongated body 514 could be configured to releasably engage or interlock with one another when the CSI 6 reaches the proper position along the body 514. A specially formed CSI 6 which includes such an interlocking structure is included within the scope of the invention. One or more additional longitudinal markers (not shown) could be provided along the body 514, distal to the marker 539, to indicate other relative positions of the CSI 6 and the body 514, such as the position at which the retractable arms 524 are exposed outside the CSI 6.

As illustrated in Figures 2-4B, the suturing device 520 includes a single, resilient suture clasp member 500 attached to the actuating rod 50. This resilient suture clasp member 500 is preferably of a unitary construction as shown. The suture clasp member 500 comprises a center or hinge portion 542 and two suture clasp arms 524 (one for each needle 546). Each suture clasp arm 524 has a suture clasp 544 at the end thereof.

The hinge portion 542 of the suture clasp member 500 acts as a "living hinge" because it has a memory which causes the member 500 to return to a partially open, unretracted position (Figure 3) when a force (applied

via rod 50) is released. This can be seen in Figures 2 and 3. In Figure 3, the suture clasp member 500 is deployed in the artery 16 in its predisposed (relaxed or natural) position. In Figure 2, the suture clasp member 500 is retracted into the suture introducer head 522 in its compressed (stressed or tensed) position. The arms 524 are moved to the retracted position by applying a distal force to the actuator rod 50, which causes the arms to contact deflection surfaces 518 (Figure 3).

This suture clasp member 500 is preferably composed of a resilient shape memory material such as NITENOL. The suture clasp member 500 may alternatively be composed of another material with spring-like characteristics, such as plastic, spring steel, stainless steel or any variations thereof. Further, the suture clasp member 500 could be composed of two arms that are hingedly connected to the actuating rod 50 without the use of a resilient hinge, as shown in Figures 4C and 4D and described below.

The living hinge configuration is easily adaptable to having three arms spaced at 120 degrees or four arms (as in Figures 19 and 20) spaced at ninety degrees. If there are three arms, then there are preferably 3 needles 546 and six lumens in the elongated body 514. Thus, other configurations and numbers of arms can be incorporated into the device to accomplish the specific needs of the application.

The needles 546 are flexible and preferably made from a material with shape memory, such as SUPERFLEX NITENOL. Alternatively, the needles 546 may be composed of spring steel, surgical stainless steel or any variation thereof. The diameter of the needles 546 is preferably about 0.019 inches, but needles with other diameters may be used in accordance with the present invention.

When the needles 546 are advanced distally and come in contact with the needle insertion guides 512, the needle insertion guides 512 cause the needles 546 to bend radially outward. The needles 546 also preferably further bend slightly (radially outward) when they come in contact with the angled surfaces 545 of the suture clasp arms 524, as shown in Figure 8. When the needles 546 are retracted into the needle lumens 516, they resume a straight configuration as a result of their resiliency. Although the embodiment of Figures 2-9 preferably uses flexible needles which bend during deployment, it is contemplated that non-bending needles, which may be either straight or curved, could alternatively be used.

As illustrated by the cut-away views of Figures 4A and 4B, the actuating rod 50 attaches to the resilient suture clasp member 500 by a pivot pin 502. The actuating rod 50 in this configuration preferably comprises a single shaft (as shown), but may comprise a plurality of shafts in other configurations.

Figure 4C is a perspective view of a non-living hinge embodiment or a two-piece suture clasp member 501. Figure 4D is a cross-sectional view of the two-piece suture clasp member 501 and a ramp or spreader 523 within the suture introducer head 522. Alternatively, in another configuration, the hinge portion of the suture clasp member 501 is similar to a hinge portion shown in Figure 14, which is described below. The spreader 523 may be a separate piece attached within the suture introducer head 522. Alternatively, the spreader and suture introducer head 522 may comprise a single molded piece.

The length of the suture clasp arm 525 is preferably about 0.174 inches. The length of both of the suture clasp arms 525, 525' together in their fully extended position (deployed with both arms parallel to each other) is preferably about 0.288 inches. In other configurations of the suture clasp arms 525, 525', the dimensions may vary.

In Figure 4D, when the actuating rod 50 pulls the two-piece suture clasp member 501 proximally (while the suture clasp member 501 is in its retracted position), the distal edges of the spreader 523 come in contact with the tips of the suture clasp arms 525, 525'. The spreader 523 causes the two suture clasps arms 525, 525' to open radially outward relative to the actuating rod 50. In a preferred method of operation, the actuating rod 50 continues to pull the suture clasp member 501 proximally until the center of the suture clasp member 501 fits into the center of the spreader 523. To retract the suture clasp arms 525, 525' into the suture clasp member's retracted position, the actuating rod 50 is advanced distally, and the interior edges 518 of introducer head 522 come in contact with the suture clasp arms 525, 525.' The interior edges 518 of introducer head 522 cause the two suture clasp arms 525, 525' to retract radially inward relative to the actuating rod 50. The general use and operation of the two-piece suture clasp member 501 is similar to the use and operation of the one-piece suture clasp member 500 shown in Figure 4A, as described below.

The proximal portion of the suturing device 520 preferably includes a handle which allows the physician to externally operate the suture clasp arms 524 and the needles 546 inside the blood vessel 16. This handle preferably has three actions: a first action in which the actuating rod 50 applies a proximal force to the hinge portion 542 to deploy and maintain the arms 524 in a fully outward position (Figure 8); a second action to advance the needles 546 distally (Figure 8) and pull the needles 546 back proximally using one or more springs; and a third action in which the actuating rod 50 applies a distal force to the hinge portion 542 to retract the arms 524 (Figures 2, 4D or 9).

Alternatively, the handle may be a 2-action handle in which one of the two actions is a combination of two of the three actions described above for the 3-action handle. For example, in a first action, the actuating rod 50 applies a proximal force to the hinge portion 542 to deploy and maintain the suture clasp arms 524 in a fully extended state of Figure 8. With the arms 524 in this fully extended position, the needles 546 automatically advance distally (Figure 8) and retract proximally to capture the looped ends of the suture 40. In a second action for this 2-action handle, the actuating rod 50 applies a distal force to the hinge portion 542 to retract the suture clasp arms 524 (Figures 2, 4D or 9). This 2-action handle is suited for physicians with more experience in operating this suture device 520. It will be apparent to one of ordinary skill in the art that a 1-action handle or a 4-action handle (inserting and withdrawing the needles 546 as two separate actions) could be used, or that separate handles or triggers could be provided for different actions. Several different handle designs are described below.

Figure 10 is a cross-sectional view of a handle 550 according to one embodiment of the invention. The handle is operatively attached to the proximal end of the hollow elongated body (shown in dashed lines), and may be used with any of the embodiments of the device disclosed herein. Figure 11 is a cross-sectional, cut-away perspective view of the handle 550 of Figure 10. Figure 18 is a perspective view of an entire device 520 which includes the handle 550 of Figure 10.

The handle 550 comprises an actuating rod aperture 551, a main housing 552, a pair of finger grips 554, a suture clasp arm piston 556 with a locking groove 576, a needle piston 560 with at least one raised key portion 562, a releasor 568 with a locking stopper 572, a pivot pin 570, a releasor support 574, a compression spring (not shown) operatively positioned in a spring recess 578 between the suture clasp arm piston 556 and the needle piston 560, a needle piston support cylinder 580 with at least one grooved recess 564 and needle clamps 584.

In one configuration, the housing 552 is attached to or is a continuation of the hollow elongated body 514 of Figure 2 or the single suture insertion and retraction housing 515 of Figure 9 or the suturing device of Figure 13A. In another configuration, the housing 552 is separate from the hollow elongated body 514 (Figure 2) or the single suture insertion and retraction housing 515 (Figure 9) or the device of Figure 13A. In this configuration, the actuating rod 50 connects the housing 552 with the hollow elongated body 514 (Figure 2) or the single suture insertion and retraction housing 515 (Figure 9) or the device of Figure 13A.

A proximal portion of the actuating rod 50 (as shown in Figures 2, 4D or 9) slides through the actuating rod aperture 551 at the distal end of the housing 552. The proximal end of the actuating rod 50 is attached to the distal end 558 of the suture clasp arm piston 556, which is slidably received within the main housing 552. A compression spring (not shown) resides in the spring recess 578 of the housing 552 between the suture clasp arm piston 556 and the needle piston 560 and simultaneously exerts two forces: a distal force on the suture clasp arm piston 556; and a proximal force on the needle piston 560.

The needle clamps 584 of the needle piston 560 hold the proximal ends of the needles 546. The needle piston 560 is slidably received within a distal portion of the housing 552. The needle piston support cylinder 580 is attached to the housing 552 and preferably does not move relative to the housing 552.

The releasor 568 pivots radially inward and outward on the pivot pin 570. The releasor support 574 exerts a radially outward force on the releasor 568. This force causes the releasor 568 to pivot and the locking stopper 572 to fall into the locking groove 576 of the suture clasp arm piston 556 when the locking groove 576 is aligned to receive the locking stopper 572. The releasor support 574 is preferably made of a resilient shape memory material such as NITENOL. The releasor support 574 may alternatively be composed of another material with spring-like characteristics, such as plastic, spring steel, stainless steel or variations thereof. Other embodiments of the handle are described below with reference to Figures 12, 21 and 22.

The use and operation of the device 520 and the handle 550 will now be described in further detail with reference to Figures 1A-11. In operation, with the CSI 6 extending into the patient's artery 16 (not shown), the physician inserts the distal portion of the device through a CSI 6 and into the artery 16 (Figures 1A-1B), such that the needle ports remain outside the artery 510. The CSI 6 is then partially withdrawn proximally along the elongated body 514 of the suturing device 520 to remove the CSI 6 from the artery 16 and expose the needle apertures 510, as shown in Figure 2. The distance of the partial removal of the CSI 6 (proximal relative to the elongated body 514) is substantially less than the length of the elongated body 514 within the flesh 14. There are one or more markings 539 (Figure 7) on the exterior surface of the elongated body 514 which indicate how far the physician should withdraw the CSI 6 to expose the needle apertures 510. The ability to insert and withdraw the device 520 through

the CSI 6 has the important advantage of reducing disturbance or damage to the surrounding flesh 14 of the patient's thigh 12 and the vessel incision 26.

The distal end 504 of the introducer head 522 has a smooth, rounded surface to prevent injury to the opposite vessel wall 506 when inserting the introducer head 522. In addition, the blood flow in the artery 16 is uninterrupted because the introducer head 522 does not occlude the artery 16. The physician may use the aperture 540 at the distal end of the suture introducer head 522 and the bleed back lumen 534 to determine when the distal end 504 of the suture introducer head 522 is in the artery 16.

While the introducer head 522 is inserted into the artery 16 as in Figure 2, the actuating rod 50 holds the resilient suture clasp member 500 in its compressed position within the introducer head 522. The actuating rod 50 applies a downward force while the interior edges 518 of the introducer head 522 apply an inward force on the two suture clasp arms 524. The combination of these two forces cause the hinge portion 542 of suture clasp member 500 between the two arms 524 to elastically deform or compress. The suture clasps 544 hold the looped ends of a suture 40 in the angled slot of the suture clasps 544 as shown in Figures 2 and 4A. The looped ends of the suture 40 are held securely by the suture clasps but are positioned for easy removal by the suture catches 38 of the needles 546.

When the distal portion of the device 520 is properly positioned in the blood vessel 16 (as in Figure 2 or 9), the physician may deploy the suture clasp arms 524 (Figure 3) by pulling the finger grips 554 in a proximal direction relative to the housing 552 (Figure 11). A physician may pull the suture clasp arm piston 556 proximally by placing the physician's index and middle finger around the finger grips 554 and pushing on the proximal end 582 of the housing 552. This action is similar to operating a standard syringe. This motion compresses the spring (not shown) in the spring recess 578 of the handle 550 in a proximal direction. As the suture clasp arm piston 556 moves proximally, the actuating rod 50 moves in a proximal direction relative to the elongated body 514 or housing 515. This is shown by the arrows in Figure 3. This motion causes the suture clasp member 500 to deploy or open to its predisposed or natural position as shown in Figure 3. The suture clasp arms 524 deploy out of the introducer head 522 into the blood vessel 16 through two suture clasp arm apertures 508 (Figure 3), one on either side of the introducer head 522.

When the physician pulls the suture clasp arm piston 556 a certain proximal distance relative to the housing 552, the locking stopper 572 at the distal end of the releasor 568 moves radially inward and falls into the locking groove 576 of the piston 556. The locking stopper 572, in combination with the locking groove 576, prevents the suture clasp arm piston 556 from advancing distally. The force of the spring in recess 578 prevents the suture clasp arm piston 556 from moving proximally. The locking of the suture clasp arm piston 556 stabilizes the suture clasp arms 524 in a locked position before the needles 546 are advanced distally.

In this locked position, the suture clasp arms 524 preferably have reached their fully extended position, as shown in Figure 8. In the fully extended position, the actuating rod 50 (attached to the suture clasp arm piston 556) has pulled the resilient suture clasp member 500 up, and the proximal inside edges 536 of the aperture 508 have come in contact with the arms 524 of the suture clasp member 500. This is shown in Figure 8. The pulling of the

actuating rod 50 and the stationary inside edges 536 of the apertures 508 cause the arms 524 to bend backward until the arms 524 are longitudinally aligned with each other, as shown in Figure 8. Thus, the resilient suture clasp member 500 is deformed from its natural configuration again, but this time in an extended position instead of a compressed position. In this extended position, the physician may move the suturing device 520 proximally so that the arms 524 touch the interior of the vessel wall 22 while the needles 546 advance distally and capture the ends of the suture 40 from the suture clasps 544.

Next, the physician twists the needle piston 560 clockwise or counter-clockwise until the raised key portion 562 of the needle piston 560 matches the grooved recess 564 of the needle piston support cylinder 580. The grooved recess 564 of the needle piston support cylinder 580 allows the raised key portion 562 of the needle piston 560 to advance distally. Otherwise, the needle piston 560 may not be advanced distally if the raised key portion 562 does not match the grooved access 564. The needle piston support cylinder 580 and the raised key portion 562 of the needle piston 560 prevent the needles 546 from advancing distally prematurely or improperly. Premature or improper insertion of the needles may cause damage to the patient's surrounding tissue 14 (Figure 1B) or the blood vessel 16.

When the raised key portion 562 of the needle piston 560 matches the grooved recess 564 of the needle piston support cylinder 580, the physician may advance the proximal end of the needle piston 560 (with the physician's thumb or palm) in a distal direction relative to the proximal end 582 of the housing 552. This motion compresses the spring in the spring recess 578 in a distal direction. When the needle piston 560 advances distally, the needles 546 and the suture catches 38 on the needles (Figure 8) also advance distally.

The paths taken by the needles 546 are illustrated in Figure 8. The needles 546 slide along the needle housings 516 (or needle lumens) and out of the suture device 520 through needle apertures 510. When the needles 546 come in contact with the needle insertion guides 512, the needles 546 begin to bend radially outward. As the needles 546 exit, they are guided at a radially outward, acute angle away from the actuating rod 50 by the needle insertion guides 512. The angle of the needle deflection is preferably 13.2 degrees. Deflection angles in the ranges of 10 to 15 degrees and 5 to 20 degrees are also contemplated.

The needles 546 then penetrate the vessel wall 22 at an angle and create incisions 248 on either side of the main vessel incision 26. The needles 546 also preferably bend slightly (radially outward) when they come in contact with the suture clasp arms 524 as the result of contact with angles surfaces (Figure 8) of the suture clasp arms. The combination of the suture clasps 544 and the suture catches 38 on the needles 546 creates a lock on the looped ends of the suture 40, such that the suture ends will not fall off while the needle 546 engages the suture clasp member 500.

The physician advances the needle piston 560 distally until the resistance of the compression spring prevents the needle piston 560 from advancing any further distally. In this position, the needles 546 are sufficiently advanced in the blood vessel 16 such that when the needles 546 are pulled back proximally, the suture catches 38 on the needles 546 will catch the looped ends of the suture 40 from the suture clasps 544. As shown in Figure

8, the clasp arms 524 hold the suture loops away from the suture introducer head 522, so that the needles 546 pierce the vessel 22 and catch the suture loops outside the perimeter of the suture introducer head 522.

After the physician advances the needle piston 560 to its farthest distal position, the physician releases the needle piston 560. The compressed spring causes the needle piston 560 to immediately spring back proximally. This motion causes the distal portion of the needles 546 to immediately spring back proximally into the needle housing 516 with the looped ends of the suture 40 attached to the suture catches 38.

The suture catches 38 on the needles 546 catch the suture loops held by the suture clasps 544 and pull the ends of the suture 40 up through the punctured holes 248 when the needles 546 are retracted proximally. When the needles 546 are retracted into the needle lumens 516, they resume a straight configuration. As the needles 546 retract, the length of the suture 40 is released (as a result of the tension caused by the retracting needles 546) from where it resided in the suture lumen 532, through an aperture 540 at the distal end 504 of the suture introducer head 522 and into the artery 16.

To retract the suture clasp arms 524 (of Figures 2, 4D or 9), the physician presses the proximal portion of the releasor 568 in a radially inward direction. This motion causes the releasor 568 to pivot. The locking stopper 572 moves radially outward and releases the locking groove 576. The force of the compressed spring causes the suture clasp arm piston 556 and the actuating rod 50 to advance distally. Together with the proximal interior edges 518 of the introducer head 522, the downward force of the actuating rod 50 causes the resilient suture clasp member 500 to retract into its compressed position. As shown in Figures 5 and 6, the suture clasp arms 524 retract into respective apertures or grooves 508 on the exterior surface of the introducer head 522. In this retracted state, the arms 524 are substantially parallel with the elongated body 514. As Figure 5 illustrates, the exterior surfaces of the arms 524 are flush with the exterior surface of the introducer head 522. This reduces the likelihood that the arms 524 will catch on the vessel wall 22, flesh 14 or CSI 6 during withdrawal. The device 520 is now ready for removal from the blood vessel 16.

The physician withdraws the suturing device 520 out of the blood vessel 16 and out of the flesh 14 of the patient's thigh 12 via the CSI 6. After the device 520 is withdrawn (and with the CSI 6 still in the flesh 14), the physician pulls the ends of the suture 40 and closes the main vessel incision 26. The physician then ties at least one knot with the ends of the suture 40 and slides or pushes the knot(s) down through the CSI 6 to the vessel incision 26. Alternatively, the physician may fasten a small, circular or flat stainless steel clip (not shown) to the ends of the suture 40 and slide the clip down through the CSI 6 to the vessel opening 26 to close the opening 26. The physician then cuts the unused ends (extra length) of the suture 40 and removes the cut portions. The physician then removes the CSI 6 from the patient's thigh 12.

The radial deployment of the suture clasp arms 524 (Figures 2-3 and 8) from the sides of the suturing device's body, without extending beyond the distal end 504 of the device 520, reduces the likelihood that the suture clasp arms 524 will contact and damage the inner vessel wall 506 opposite the incision 26.

The locked position of the suture clasp arms 524 (as described above with reference to Figure 8) provides a stable base or foundation for holding the looped ends of the suture 40 while the needles 546 come in contact with

the suture clasp arms 524 and capture the suture 40. The suture clasp arms 524 are preferably locked in the locked position by the proximal force of the actuating rod 50, the stationary inside edges 536 of the apertures 508, and the protrusions 528 at the 'elbow' end of each arm 524 (Figure 8). Specifically, when the suture clasp arms 524 become substantially parallel with each other (i.e., each arm 524 is at an angle of approximately 90 degrees from the actuating rod 50), the protrusions 528 at the 'elbow' end of each arm 524 come into contact with each other and preferably prevent the arms 524 from bending any further than the configuration shown in Figure 8. The protrusions 528 preferably prevent the suture clasp member 500 from moving or bending unintentionally (opening any farther) when the needles 546 are inserted distally and come in contact with the suture clasp arms 524. This reduces the risk of the looped ends of the suture 40 being accidently displaced from the suture clasps 544 when the needles 546 engage the suture clasps 544. Thus, the combination of forces asserted by the actuating rod 50, the proximal inside edges 536 of the aperture 508 and the two protrusions 528 sustain the suture clasp arms 524 in a rigid, locked position to facilitate the proper removal of the suture looped ends from the suture clasps 544.

The shape and position of the angled slits of the suture clasps 544 in Figures 2-9 provide another advantage. The slits of the suture clasps 544 in Figures 2-9 are angled in a proximal, radially inward direction. Thus, the face of the looped ends of the suture 40 face in a proximal, radially inward direction. This configuration reduces the likelihood that the looped ends of the suture 40 will improperly or prematurely fall off the suture clasps 544. When the needles 546 engage the suture clasp arms 524, preferably the only direction the looped ends may move is in a proximal, radially inward direction, which is in the opposite direction of the inserted needles 546. When the needles 546 retract proximally (as shown in Figure 8), the looped ends reliably fall into the suture catches 38 of the needles 546. The proximal movement of the needles 546 in the embodiments in Figures 2-9 causes the suture catches 38 on the needles 546 to catch the looped ends of the suture 40.

In the various embodiments described with reference to Figures 1A-9, retractable suture clasp arms are used to hold the suture 40 beyond the outer circumference of the tubular housing (and thus beyond the boundaries of the incision 26), and flexible needles 546 are used to capture the held suture 40 outside the outer circumference. In other implementations (not shown), the suture clasp assembly may be in the form of a fixed (non-moving) member which holds the suture 40 near or within the circumference of the housing. In such implementations, curved needles may be used which pierce the vessel wall outside the circumference of the housing and then "curve in" to capture the suture. The curved needles may then be withdrawn to pull the ends of the suture out of the vessel wall 22.

Figure 12 is a cross-sectional view of another embodiment of a handle 600 which may be used in place of the handle of Figure 10. The handle 600 of Figure 12 comprises a housing 602 with a spring recess 622, a pair of external finger grips 604 (only one shown in Figure 12), a suture clasp arm piston 606 with a locking groove 608, a releasor 612 with a locking head 610 and a needle piston stopper 618, a pivot pin 614, a needle piston 620 with needle clamps 616 and a spring 624.

The handle 600 also includes a second spring (not shown) which biases the releasor 612 toward a position in which the locking head 610 is engaged with the groove 608. Similar to the handle 550 shown in Figures 10 and 11, the finger grips 604 extend outside the housing 602 to allow a physician to move the piston 606 relative to

the housing 602. The proximal ends of the needles 546 in Figure 12 are attached to the needle clamps 616, which are attached to the needle piston 620. The actuating rod 50 (Figure 2) is attached to the suture clasp arm piston 606 in Figure 12.

The general operation of the handle 600 shown in Figure 12 is similar to the operation of the handle 550 shown in Figures 10-11. In Figure 12, the needle piston stopper 618 prevents the needle piston 620 from distally advancing prematurely or improperly. This function is similar to the function of the raised key portion 562 and grooved recess 564 of the handle 550 shown in Figures 10-11. In Figure 12, the physician advances the suture clasp arm piston 606 proximally against the biasing force of the spring 614 (by pulling the finger grips 604 proximally) to deploy the suture clasp arms 524 (Figure 3) until the locking head 610 of the releasor 612 moves radially inward and falls into the locking groove 608. At this point, the clasp arms 524 are in the fully deployed or open position as in Figure 8. This motion causes the proximal portion of the releasor 612 to advance radially outward until the needle piston stopper 618 is no longer blocking the needle piston 620. At this time, the physician may advance the needle piston 620 distally into the recess 622 to cause the needles 546 to advance distally and capture the suture 40. When the physician releases the needle piston 620, the spring 614 moves the needle piston proximally to the outward position, causing the needles 546 to retract with the suture 40. Finally, the physician presses the external lever portion of the releasor 612 to release the suture clasp arm piston 606; this causes the suture clasp arms 524 to return to the retracted position, so that the device 520 can be withdrawn from the artery 16.

One of ordinary skill in the art will appreciate that there are many possible configurations of this handle attached to the proximal end of the device 520. In one configuration (not shown), there are at least two springs or sets of springs (not shown), instead of the single compression spring as used by the handle 550 in Figures 10-11 and the handle 600 in Figure 12. In this embodiment with two springs, a first spring exerts a proximal force on the needles 546 while a second spring exerts a distal force on the actuating rod 50 inside the handle. In another configuration (not shown), instead of a second set of springs or a trigger, the physician manually retracts the needles 546 proximally back into the needle housing 516.

Figures 13A-17 illustrate the device of Figure 1A according to another embodiment of the invention. In this embodiment, the ends of the suture 40 are provided with special loops or fittings 41 that are configured to engage with the needles 650 (Figure 16). As shown in Figure 14A, a first suture clasp arm 630 comprises a hinge portion 636 with an aperture 642 for a pivot pin 502 (Figure 4C). The first suture clasp arm 630 further comprises a curved portion 638 for the distal end of an actuating rod 50 (as in Figure 4B) and the hinge portion of a second suture clasp arm 630' (Figure 14B). The first suture clasp arm 630 further comprises an annular recess 632 for holding a suture looped end 41, a slit 640 for the length of the suture 40, and a sloped end 634. Figure 14B illustrates the second suture clasp arm 630', which is the other half of a two-piece suture clasp member. The second suture clasp arm 630' is similar to first suture clasp arm 630 except the second suture clasp arm 630' does not have a curved portion 638 for the distal end of an actuating rod 50 (Figure 4B).

The length of the first suture clasp arm 630 is preferably about 0.174 inches. The length of both of the suture clasp arms 630, 630' together in their fully extended position (deployed with both arms parallel to each other) is preferably about 0.288 inches. In other configurations of the suture clasp arms 630, 630', the dimensions may vary.

As shown in Figures 16-17, each of the flexible needles 650 comprises an extended shaft, a penetrating distal tip 654, and a groove 652 near the distal end. The needle groove 652 acts as a detent mechanism or suture catch. In a preferred configuration, the grooves 652 extend around the complete circumference of the needles 650. In other configurations, the grooves 652 are partially circumferential along the radial edge of the needles 650. The loops 41 correspond generally in diameter to grooves 652 of the needles 650, but are sufficiently resilient to expand in diameter in response to the downward force of the needles 650.

The looped end 41 of the suture 40 may be formed by heating one end of a length of suture until the end becomes a ball-shaped configuration. The ball-shaped end is then compressed into a disc shape. A hole is then made near the center of the disc-shaped end such that the disc-shaped end forms a loop. In one configuration, the suture 40 comprises a monofilament or plastic suture material, such as prolene or declene. In one method of forming the looped end, instead of heating the end of a suture length, the suture end is simply compressed and a hole is formed thereafter. The end may be further cut or stamped into a circle shape.

In another configuration, instead of pre-forming the hole in the suture end, the actuation of the needles 650, as described below with reference to Figure 17, is used to form the hole and fasten the ends of the suture to the needles 650. In another configuration, a separately-formed loop is insert-molded, glued, crimped or otherwise attached to the end of a length of suture.

Each loop 41 may have circular configuration as shown in Figure 13A, or may have another appropriate configuration such as an oval, triangle, rectangle, hexagon, or octagon.

The general use and operation of the device of Figures 13A-17 is substantially the same as described above with reference to Figures 2-9. Specifically, the looped ends 41 of the suture 40 are placed within the annular recess 632 of the suture clasp arms 630, 630' (Figures 13A and 15). The suture introducer head 522 is inserted into biological tissue 14 (similar to Figures 1A-2), and the suture clasp arms 630, 630' are deployed radially outward (Figure 16). The penetrating flexible needles 650 pass through the biological tissue to be sutured (similar to Figure 8) and engage the suture clasp arms 630, 630' (Figure 17).

When the needle points 654 pass through the looped ends 41 of the suture 40, the looped ends 41 flex radially outward momentarily. As the needles 650 continue to advance distally, the looped ends 41 come in contact with the grooves 652. As the result of the resiliency of the loop material, the looped ends flex radially inward and fasten around the needle grooves 652, such that pulling the needles 650 proximally causes the suture ends 41 to follow the proximal movement of the needles 650. Thus, the grooves 652 serve the same general purpose as the suture catches 38 (Figure 2) described above with reference to Figures 2-3 and 8.

Figures 19-20 are perspective views of a four-arm suture clasp assembly which may be used with a device similar to the suturing device 520 of Figure 1A-2. The suture clasp assembly includes four suture clasp arms 662-

668, each of which corresponds to a respective needle (not shown) and needle port (not shown) of the device. Each of the four suture clasp arms 662-668 comprises an annular recess and a slit for the length of the suture. In one embodiment, two sutures are used with the device shown in Figures 19-20, each of which is held by a pair of suture clasp arms 662-668. Each suture has a loop at either end which is placed within one of annular recesses of a suture clasp arm 662-668. The arms 662-668 may alternatively be provided with one of the other types of suture clasp structures disclosed above.

Figures 21 and 22 illustrate a handle 700 according to another embodiment of the invention. The handle 700 comprises a thumb ring 702, a plunger 704, a plunger distal end 706, a main housing 710, a proximal aperture 708, a finger ring 712, a sloped floater peg slot 714, a floater clamp slot 715, a distal end aperture 716, a floater 720, a peg 718, a floater clamp lock 722, a floater clamp 724, a drive wire (actuating rod 50) clamp 726, a needle holder backer 728, a needle holder 730, a floater clamp peg 732, a floater clamp aperture 734, a spring 736, a plunger pegs 738, L-shaped lock recess 740 and an extrusion (hollow elongated body 514) clamp 742.

The spring 736, the floater 720, the floater clamp lock 722, the floater clamp 724, the drive wire clamp 726, the needle holder backer 728, the needle holder 730 and the extrusion clamp 732 are operatively received within the main housing 710. The shaft of the plunger 704 is slidably received through the floater 720, the floater clamp lock 722 and the floater clamp 724.

The square- or rectangular-shaped shaft of the plunger 704 fits within the square- or rectangular-shaped axial recess of the floater 720, such that rotating the plunger 702 clockwise causes the floater 720 to rotate clockwise as well. The plunger distal end 706 is adapted to snap into or otherwise attach itself into the needle holder backer 728. The plunger pegs 738 are slidably received along the L-shaped lock recess 740 formed on the interior of the main housing 710.

In a preferred configuration, the L-shaped recess lock 740, the floater peg slot 714 and the floater clamp slot 715 are all molded, carved or otherwise formed on the interior of the main housing 710. The spring 736 provides a proximal biasing force on the plunger pegs 738 and the plunger 704. The spring 736 also provides a distal biasing force on the floater 720.

The floater peg 718 is slidably received along the sloping floater peg slot 714. The distal end of the floater 720 snaps and locks into the proximal portion of the floater clamp lock 722. The floater clamp lock 722 is preferably glued, bonded or otherwise attached to the floater clamp 724. The drive wire clamp 726 fits within the aperture 734 of the floater clamp 724. The drive wire clamp 726 is glued, bonded or otherwise attached to a proximal portion of a drive wire or the actuating rod 50 of Figures 13B (or Figures 2 or 9).

The extrusion (hollow elongated body 514) clamp 742 is glued, bonded or otherwise attached to a proximal portion of the hollow elongated body 514 of Figure 13A. The needle holder 730 is preferably glued, bonded or otherwise attached to the needle holder backer 728. The proximal portion of the needles 546 of Figure 2 or the needles 650 of Figure 16 are preferably glued, bonded, molded into or otherwise attached to the needle holder 730.

The use and operation of the handle 700 will now be described with reference to Figure 21. While the handle 700 is in its initial state and shipped to end-users, the plunger pegs 738 within the L-shaped lock recess 740

prevent the plunger 704 from moving distally relative to the main housing 710. When a physician rotates the plunger 704 clockwise by twisting the thumb ring 702, the plunger pegs 738 move circumferentially along the L-shaped lock recess until the plunger pegs 738 are positioned to slide distally down the longitudinal part of the L-shaped lock recess 740.

As the physician rotates the plunger 704, the floater 720 also rotates clockwise. The peg 718 moving within the sloped floater peg slot 714 causes the floater 720 to move proximally. Because the drive wire clamp 726 is attached to the drive wire or actuating rod 50 (Figure 13A), the proximal movement of the floater 720 causes the floater clamp lock 722, the floater clamp 724, the drive wire clamp 726, and the actuating rod 50 to move proximally, such that the suture clasp arms 630, 630' deploy radially outward (Figures 13A-13B).

Once the plunger 702 is fully rotated and the plunger pegs 738 are positioned to slide distally down the longitudinal part of the L-shaped lock recess 740, the physician may advance the plunger 702 distally. The distal movement of the plunger 702 causes the needles 546 (Figure 8) or the needles 650 (Figure 16) to advance distally, penetrate the biological tissue, and engage the suture clasp arms 524, 630, 630' (Figure 8 and Figure 16).

While embodiments and applications of this invention have been shown and described, it will be apparent to those skilled in the art that various modifications are possible without departing from the scope of the invention. It is, therefore, to be understood that within the scope of the appended claims, this invention may be practiced otherwise than as specifically described.

WHAT IS CLAIMED IS:

1. A suturing device for remotely sealing an incision in a wall of a blood vessel or other biological structure, comprising:

an elongated body having a distal portion which is adapted to be inserted through the incision and into the blood vessel, the distal portion having an outer wall with first and second apertures formed therein, the elongated body further comprising first and second needle ports positioned proximal to the distal portion such that the needle ports remain outside the blood vessel when the distal portion is positioned within the blood vessel;

first and second arms which retract into and extend out from the first and second apertures, respectively, and which releasably hold a suture, the arms remotely movable to a deployed position in which the arms extend outward from the body to hold the suture away from the body; and

first and second needles which extend from the first and second needle ports, respectively, to capture the suture, the needles remotely movable between a retracted position in which the needles are housed within the body and an extended position in which the needles extend distally from the needle ports and outwardly from the body;

wherein movement of the needles from the retracted position to the extended position, and back to the retracted position, with the arms deployed within the blood vessel and holding the suture, causes the needles to pierce the blood vessel, release the suture from the arms, and withdraw a portion of the suture from the blood vessel.

2. The suturing device of Claim 1, wherein a distal section of the elongated body, including the needles and the needle ports, is configured to be percutaneously introduced into a patient through a standard catheter sheath introducer (CSI) used to perform a catheterization procedure, such that the needles may be extended and retracted to capture and withdraw the suture without removing the CSI from the patient.

3. The suturing device of Claim 2, wherein a proximal section of the elongated body includes a marker on an outer surface, the marker indicating a longitudinal position to which the CSI may be partially withdrawn to expose the needle ports.

4. The suturing device of Claim 1, wherein the needles have a substantially straight configuration when in the retracted position, and bend outward away from the body when in the extended position.

5. The suturing device of Claim 4, wherein the needle ports include needle guides which apply an outward force to the needles to cause the needles to bend outward.

6. The suturing device of Claim 1, further comprising a handle coupled to a proximal portion of the body, the handle including controls for remotely moving the needles and the arms.

7. The suturing device of Claim 1, wherein the first and second arms are interconnected by a flexible, resilient hinge, the hinge holding the arms in a partially open position when the hinge is in a relaxed state.

8. The suturing device of Claim 7, wherein the flexible hinge is coupled to an actuator shaft which extends within a lumen of the body, and wherein application of a proximal force to the actuator shaft causes the

arms to move from the partially open position to the deployed position, and application of a distal force to the actuator shaft causes the arms to move from the partially open position to a retracted position.

9. The suturing device of Claim 1, wherein outer surfaces of the first and second arms are flush with an outer surface of the body when the arms are retracted within the body.

10. The suturing device of Claim 1, wherein the first and second arms are substantially parallel to the body when retracted within the apertures.

11. The suturing device of Claim 10, wherein the first and second arms extend radially outward from the body at an angle of approximately 90 degrees when in the deployed position.

12. The suturing device of Claim 1, wherein the distal portion includes at least one blood port which is fluidly coupled to a lumen within the elongated body, the lumen extending to a proximal portion of the elongated body to allow a physician to determine whether the distal portion is in the blood vessel.

13. The suturing device of Claim 12, wherein the lumen is coupled to a pressure sensor that provides a visual indication of whether the distal portion is in the blood vessel.

14. The suturing device of Claim 1, wherein the arms are spaced proximally from a distal tip of the body, so that the arms are inhibited from contacting a wall of the blood vessel opposite the incision during deployment.

15. The suturing device of Claim 1, wherein each needle includes a groove formed circumferentially therein, the groove configured to engage a loop at an end of the suture.

16. The suturing device of Claim 1, further comprising third and fourth arms which retract into and extend from third and fourth apertures in the distal portion and releasably hold a second suture.

17. The suturing device of Claim 1, wherein the body includes at least one marker thereon to visually indicate a rotational orientation of the distal portion.

18. A method of closing an opening in a wall of a blood vessel of a patient following a catheterization procedure in which a catheter sheath introducer (CSI) is used to introduce a catheter into the blood vessel, comprising:

with the CSI inserted through the skin of the patient and into the blood vessel, introducing a distal portion of an elongated body of a suturing device through the CSI and into the blood vessel with the distal portion releasably holding a suture;

with the distal portion positioned within the blood vessel, moving the CSI proximally along the elongated body, without removing the CSI from the patient, to expose needle ports along the elongated body, the needle ports being proximal to the distal portion such that the needle ports remain outside the blood vessel; and

with the elongated body extending through the CSI, actuating a suture catch assembly of the device to cause retractable needles of the device to extend from the needle ports to pierce the blood vessel and release the suture from the distal portion, and then retract into the needle ports to withdraw a portion of the suture from the blood vessel; and

withdrawing the distal portion of the elongated body through the CSI an out of the patient.

19. The method of Claim 18, wherein the elongated body includes a marker, and the step of moving the CSI proximally comprises using the marker to properly position the CSI relative to the elongated body.

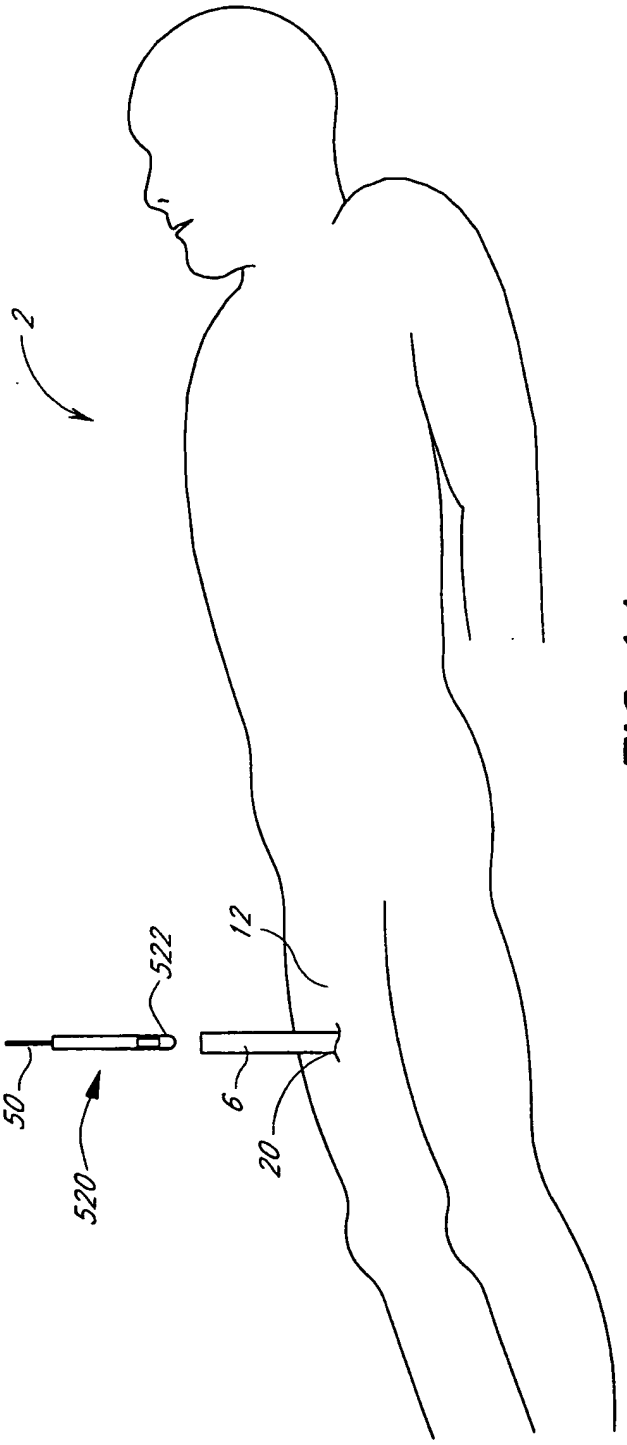

FIG. 1A

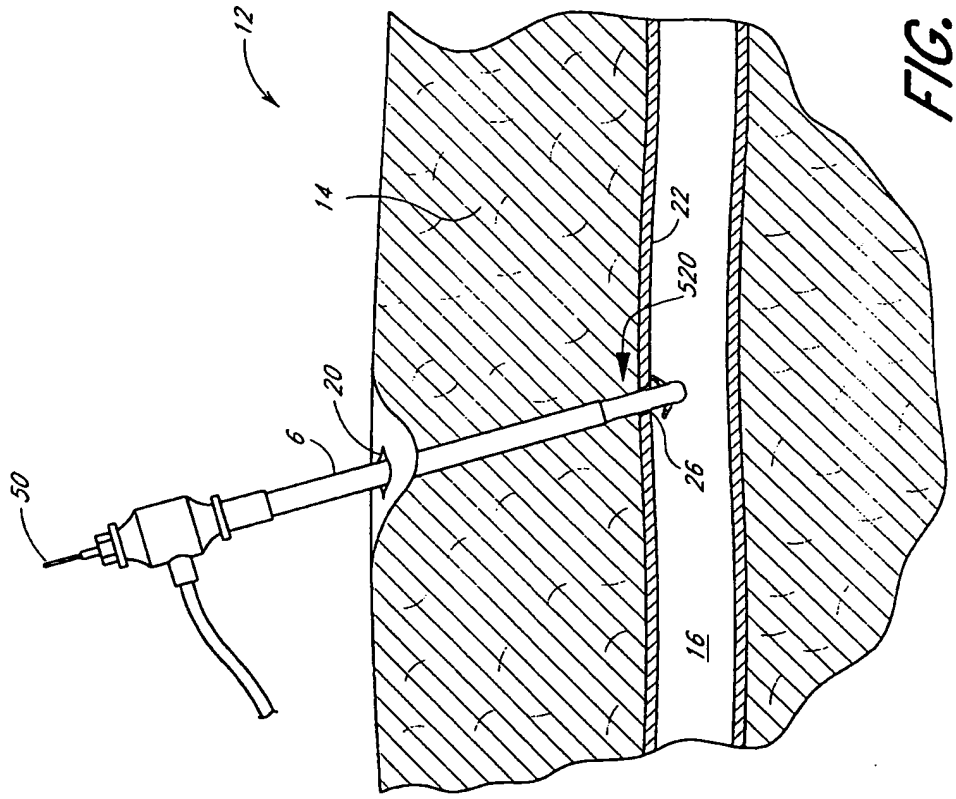

FIG. 1B

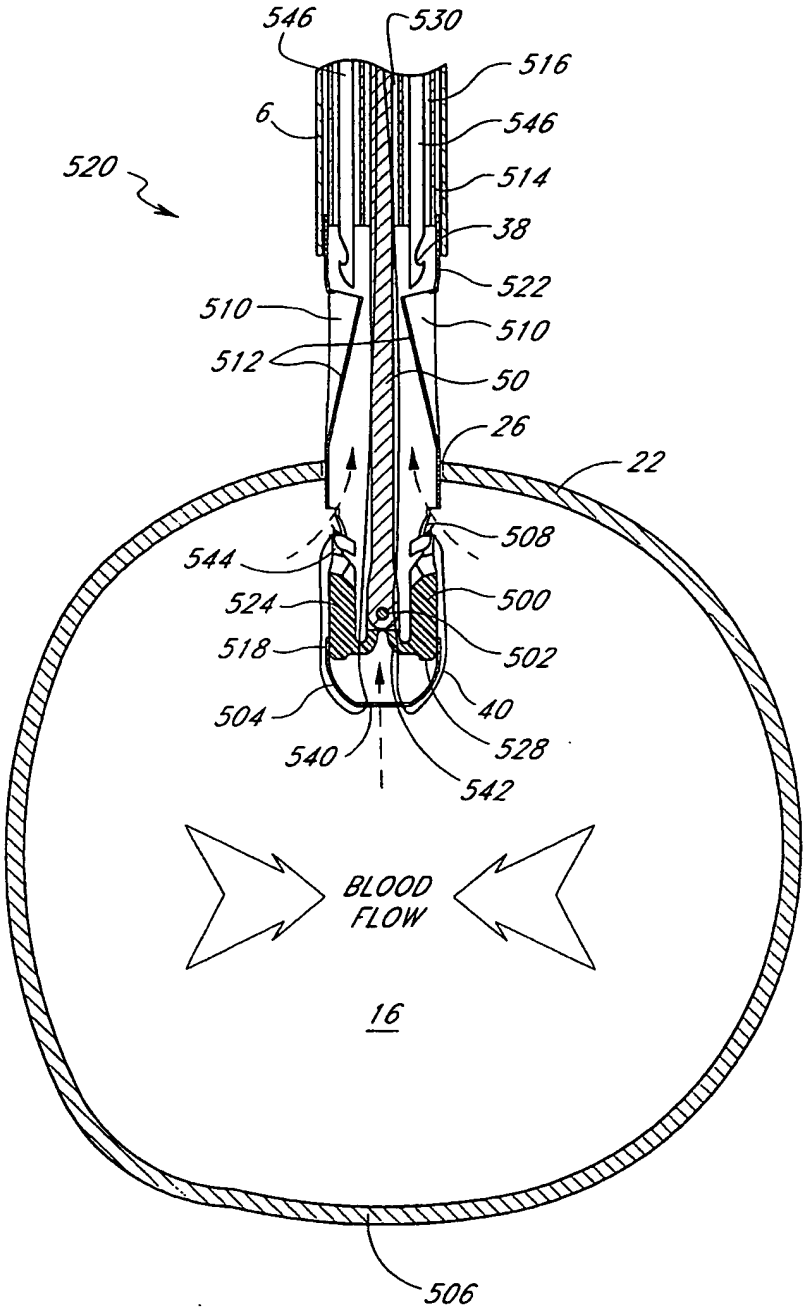
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FIG.2

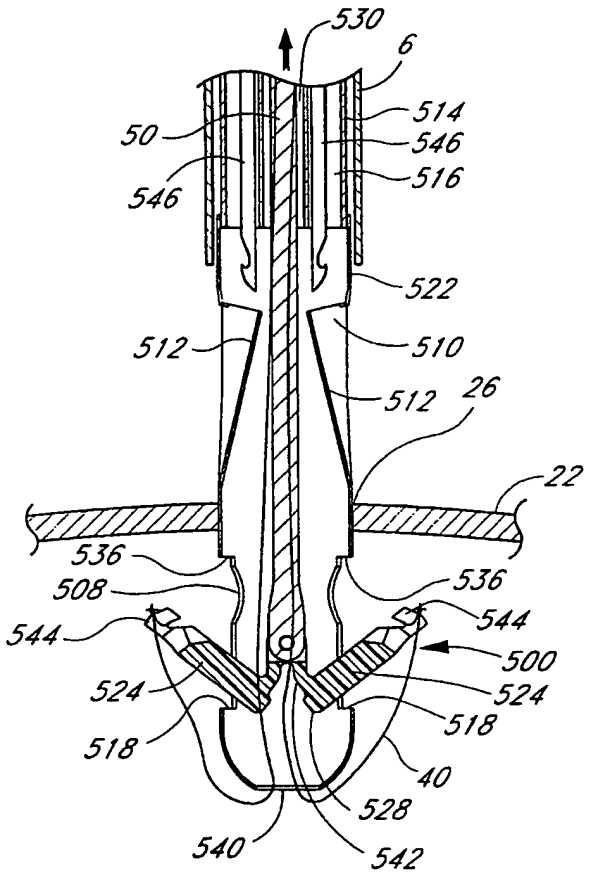
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FIG. 3

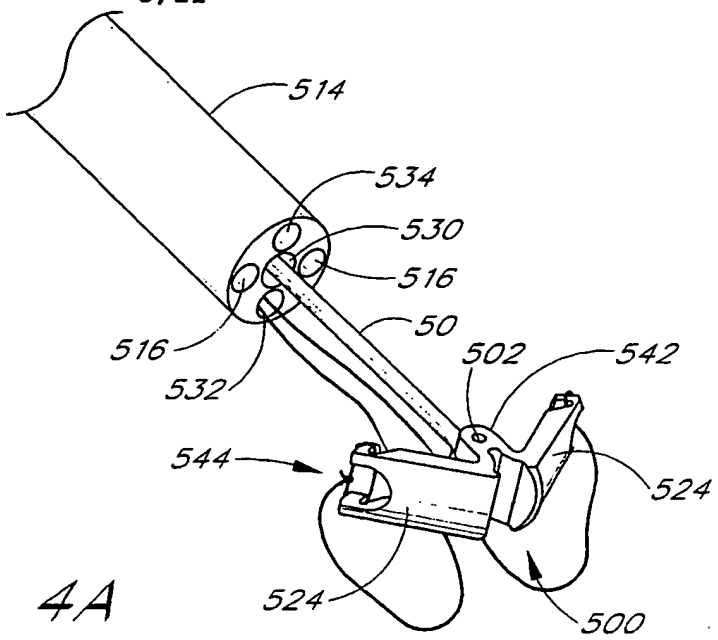
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FIG. 4A

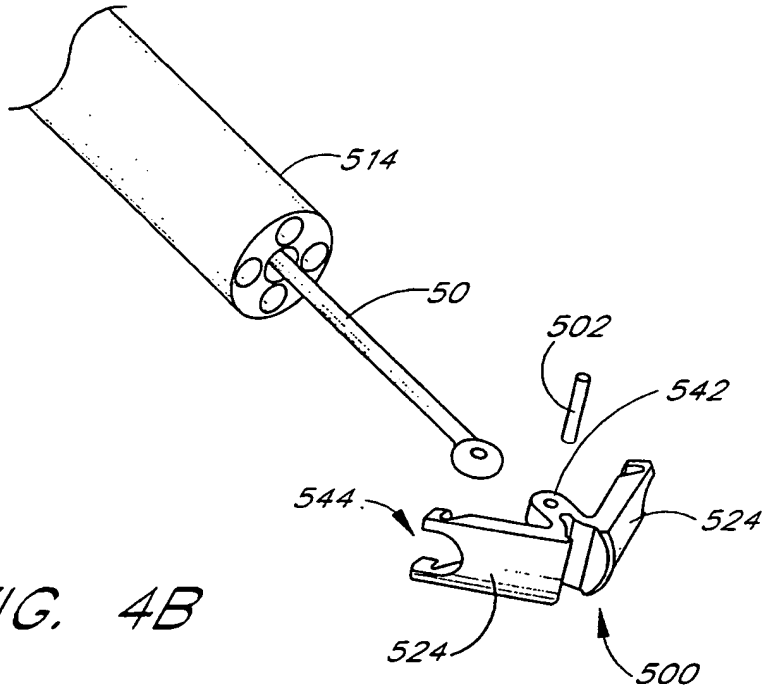
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FIG. 4B

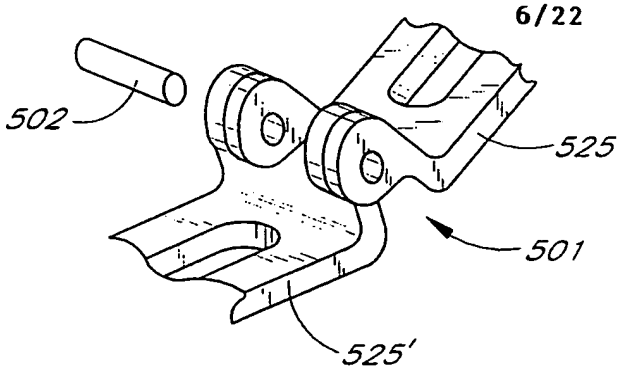
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FIG. 4C

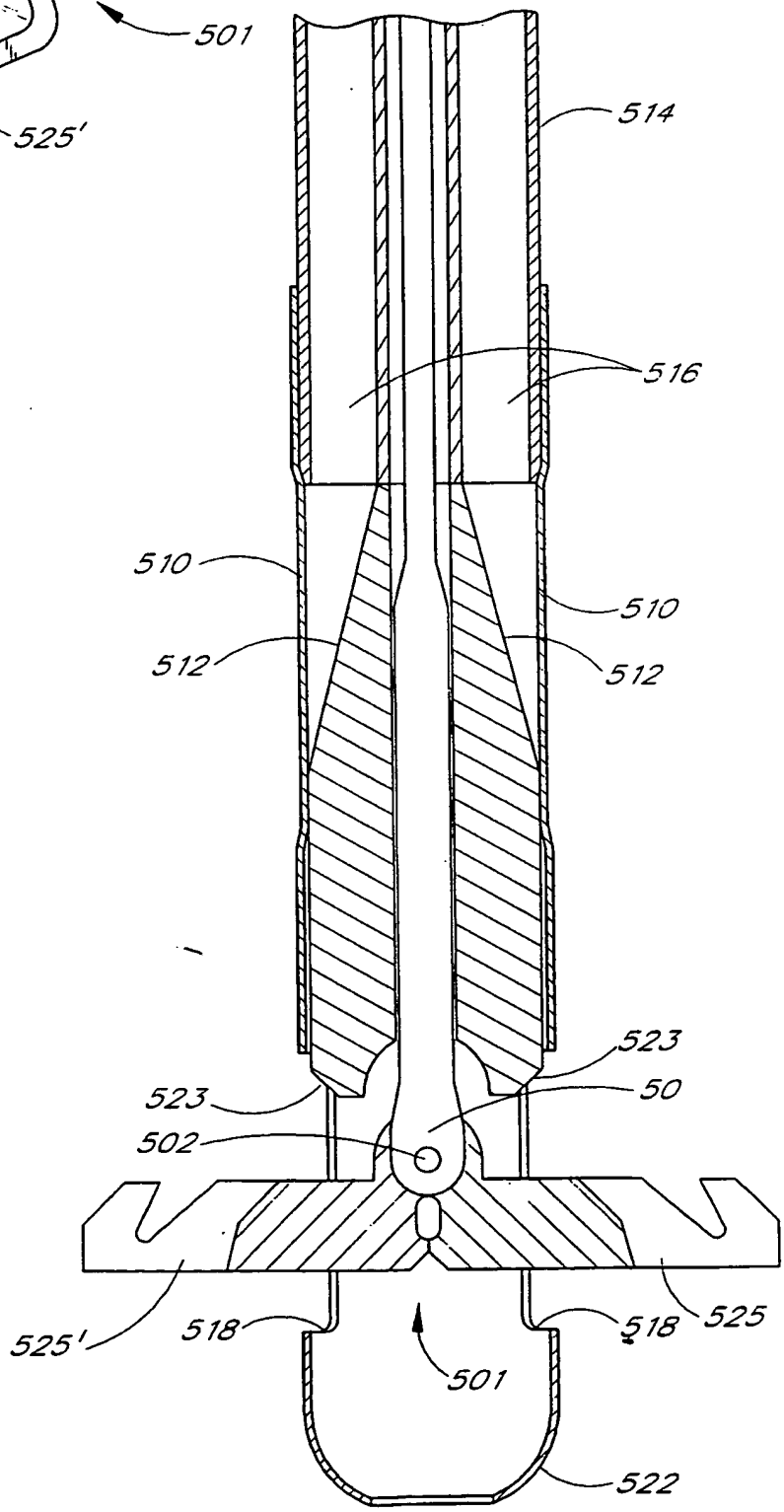
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FIG. 4D

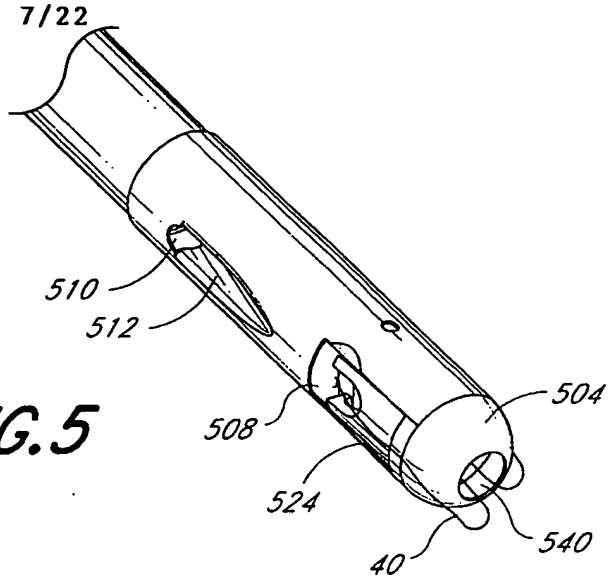

FIG. 5

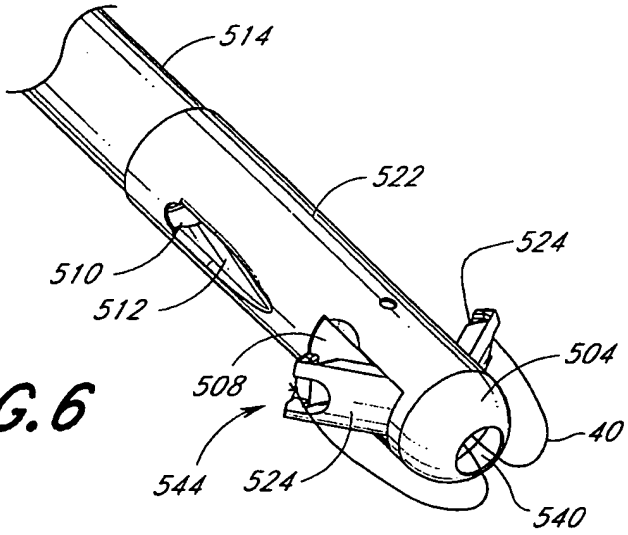

FIG. 6

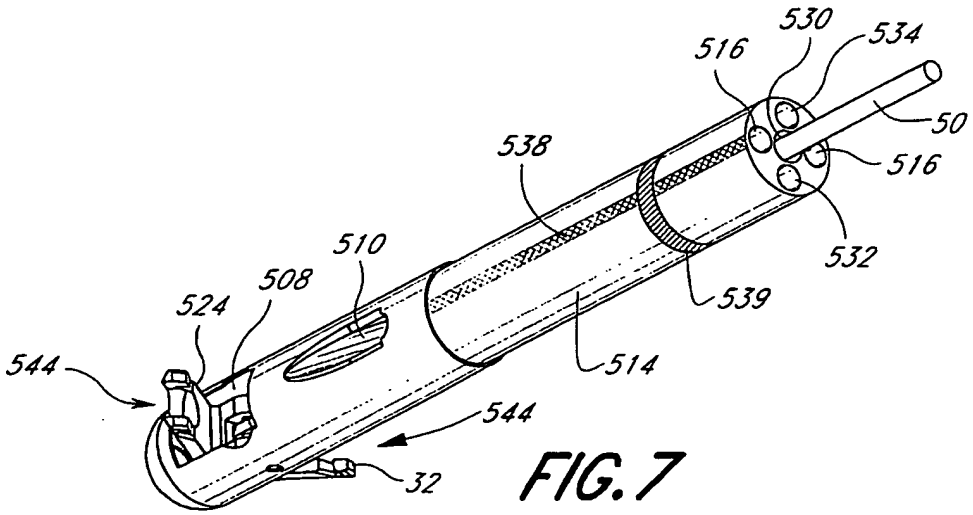

FIG. 7

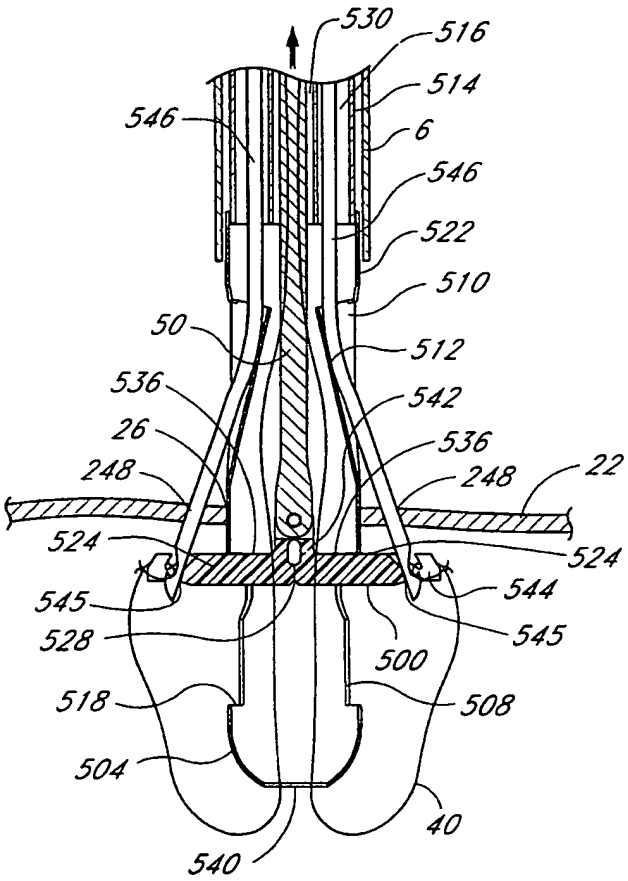
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FIG. 8

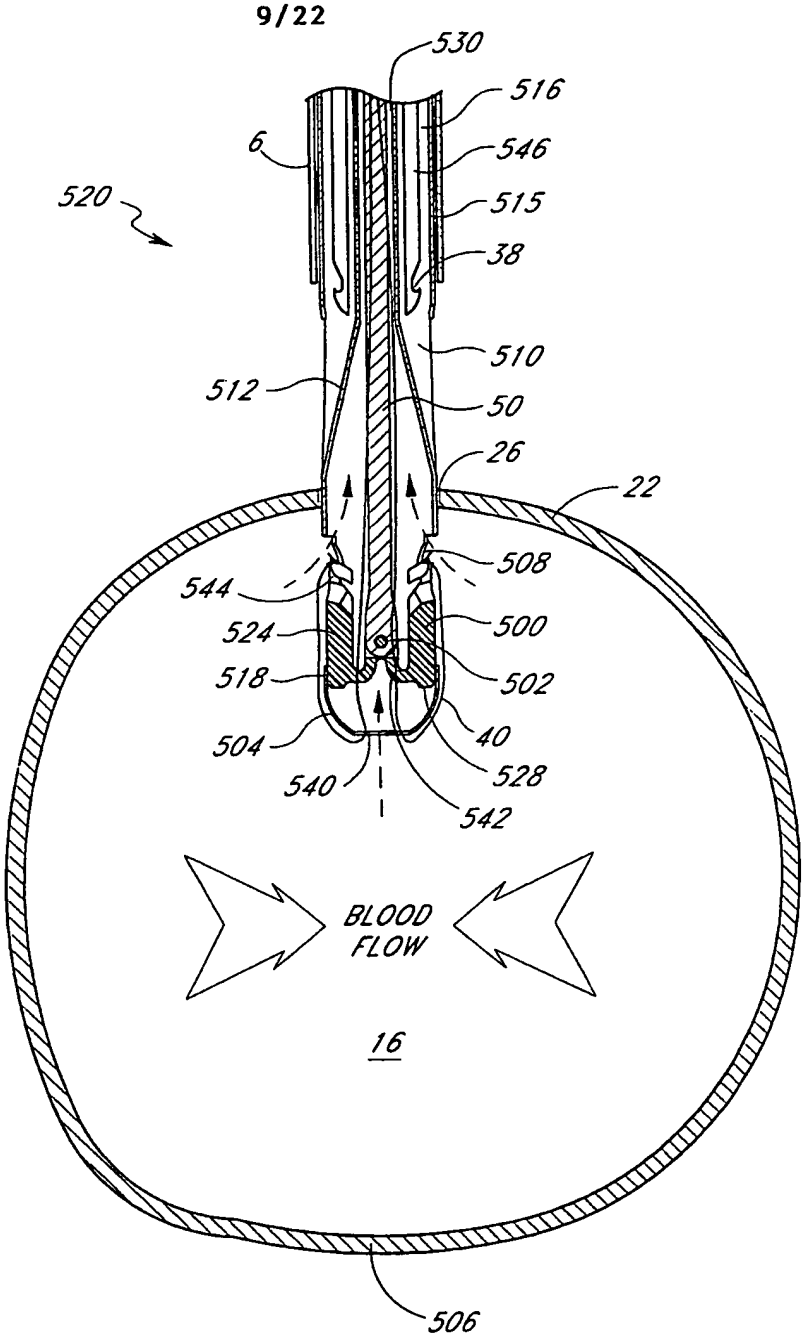
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FIG. 9

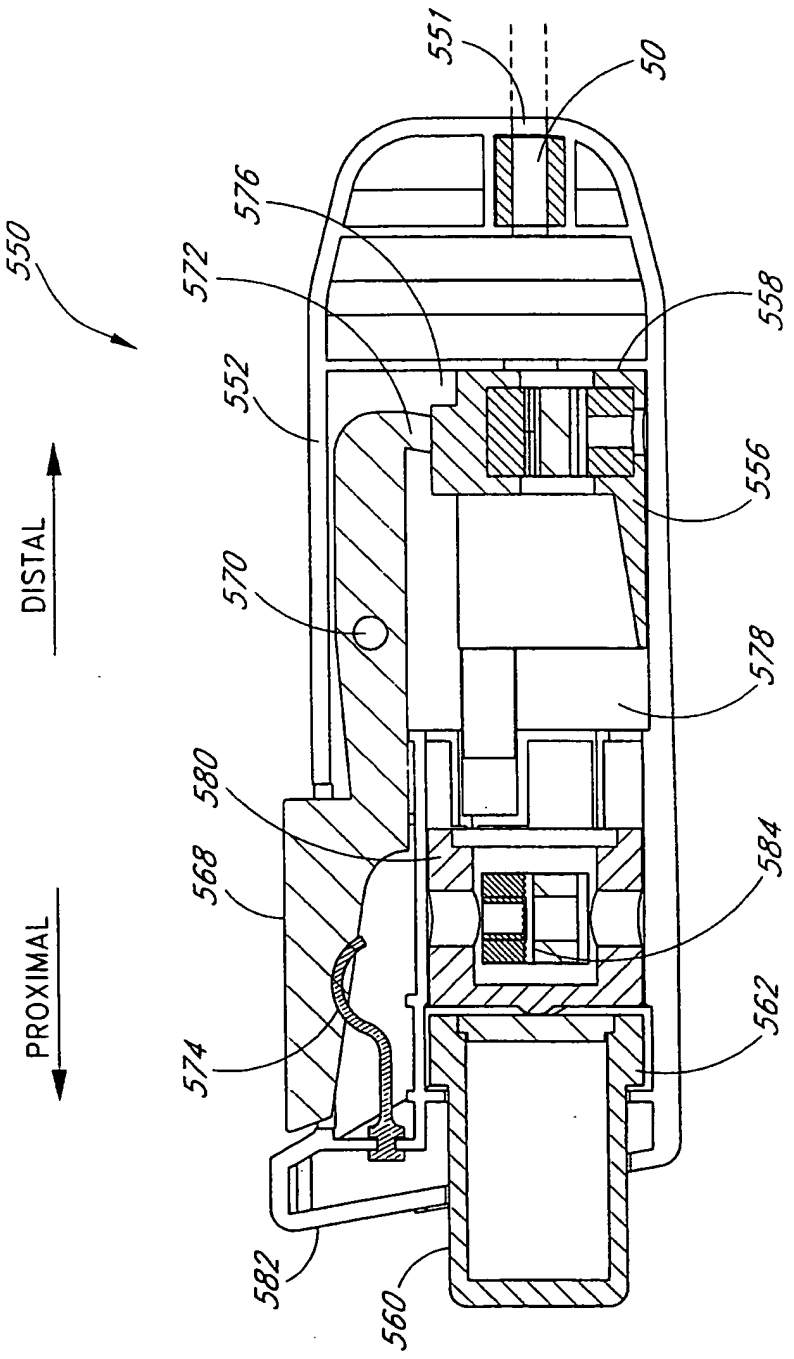
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FIG. 10

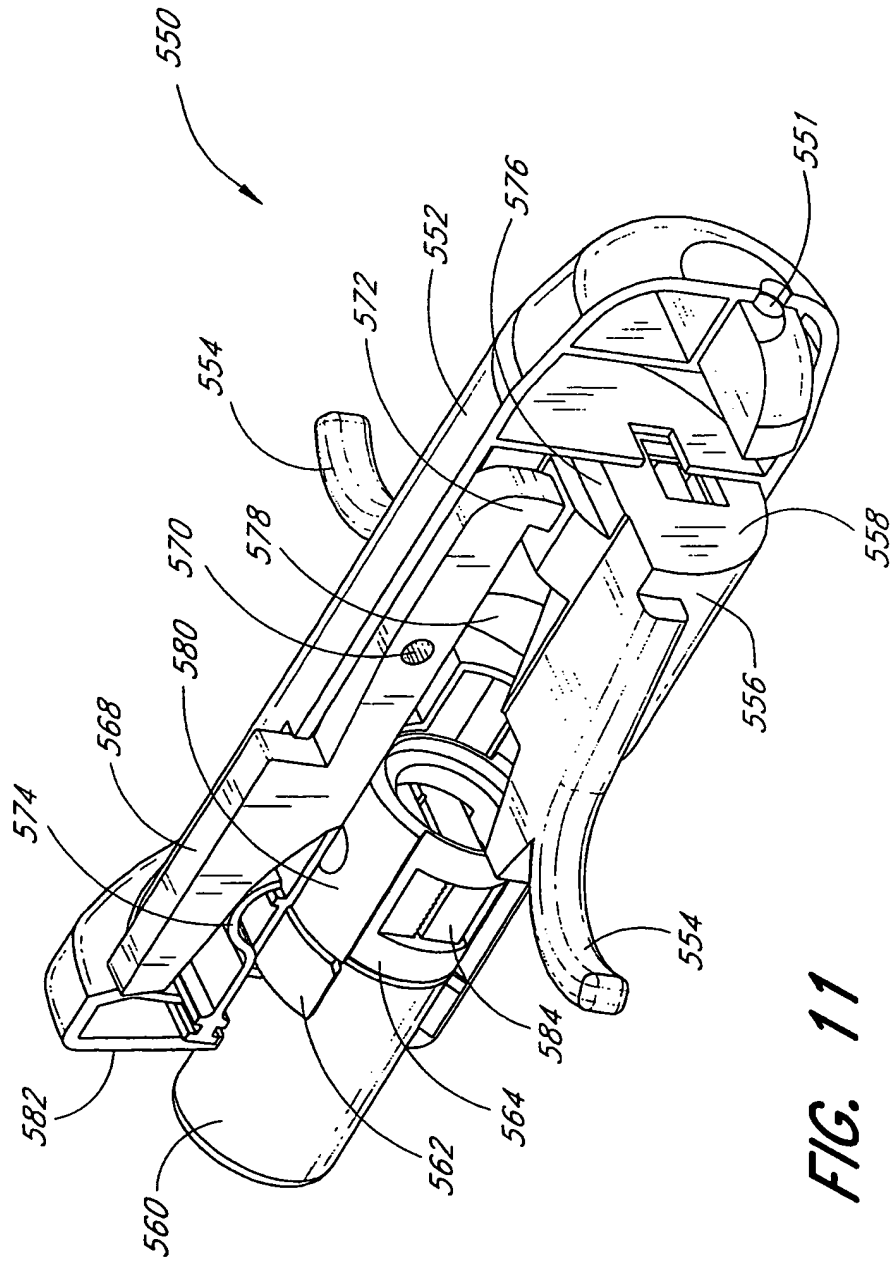
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FIG. 11

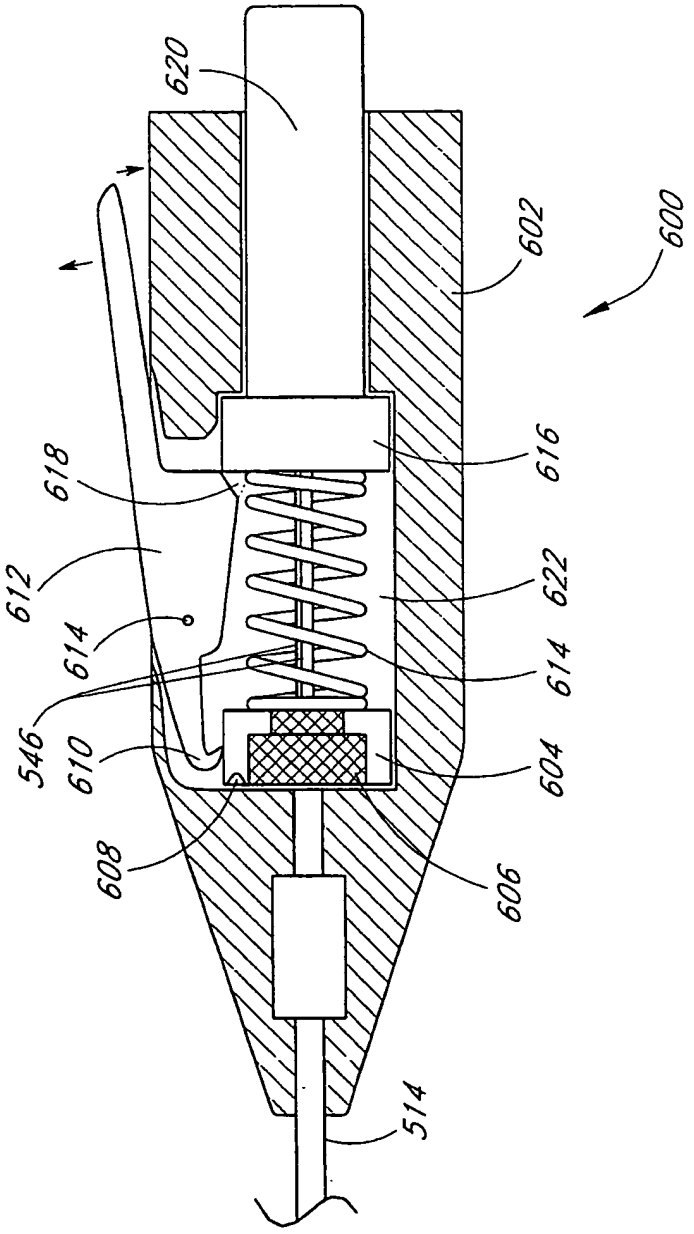

FIG. 12

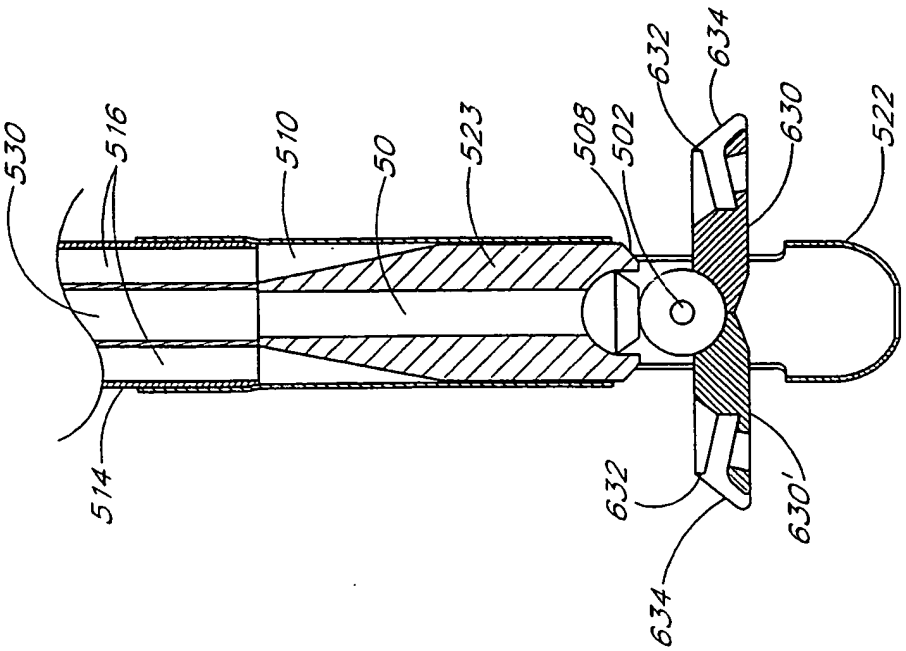

FIG. 13B

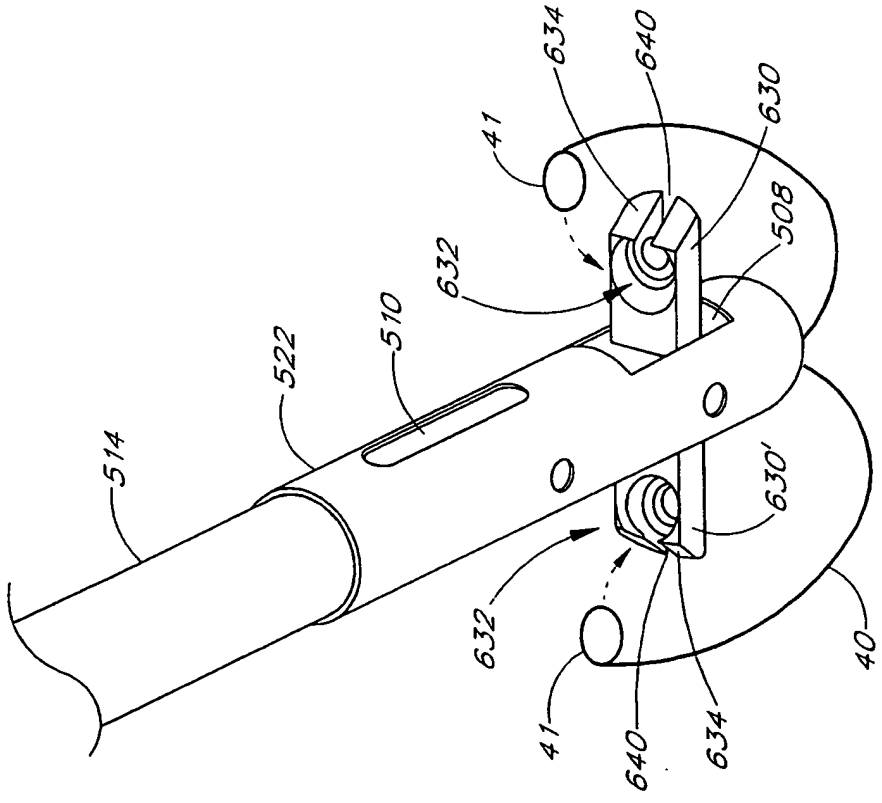

FIG. 13A

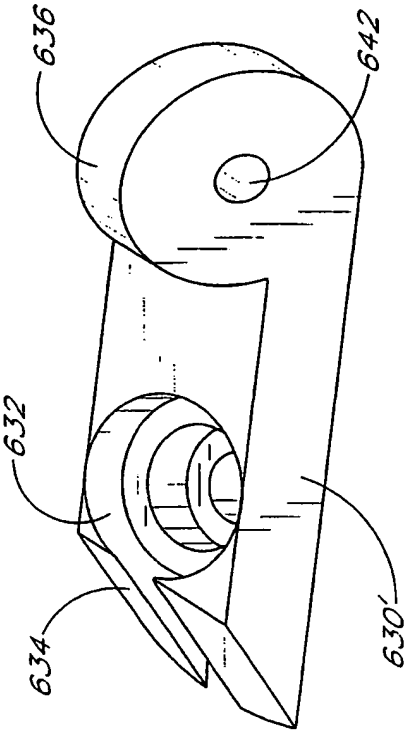

FIG. 14B

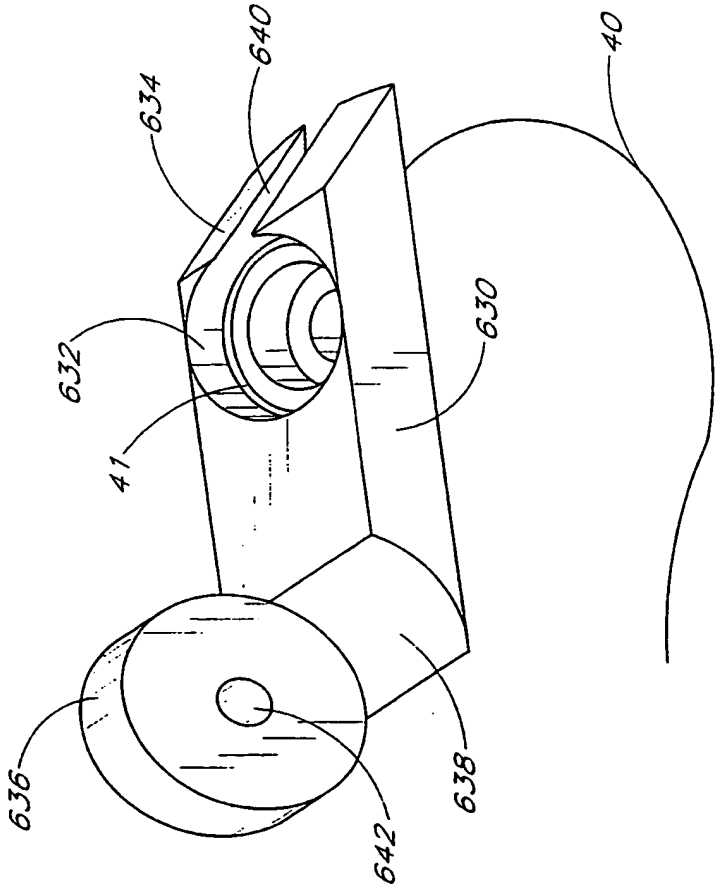

FIG. 14A

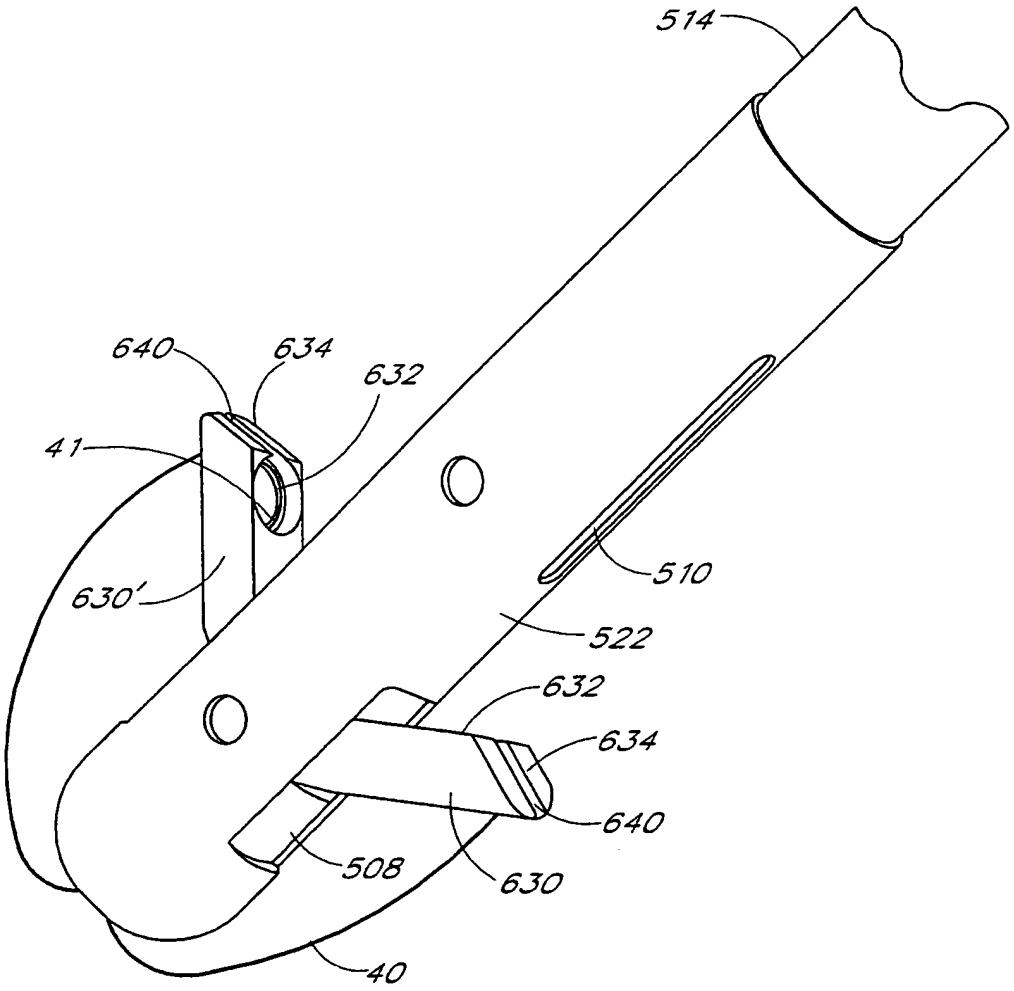

FIG. 15

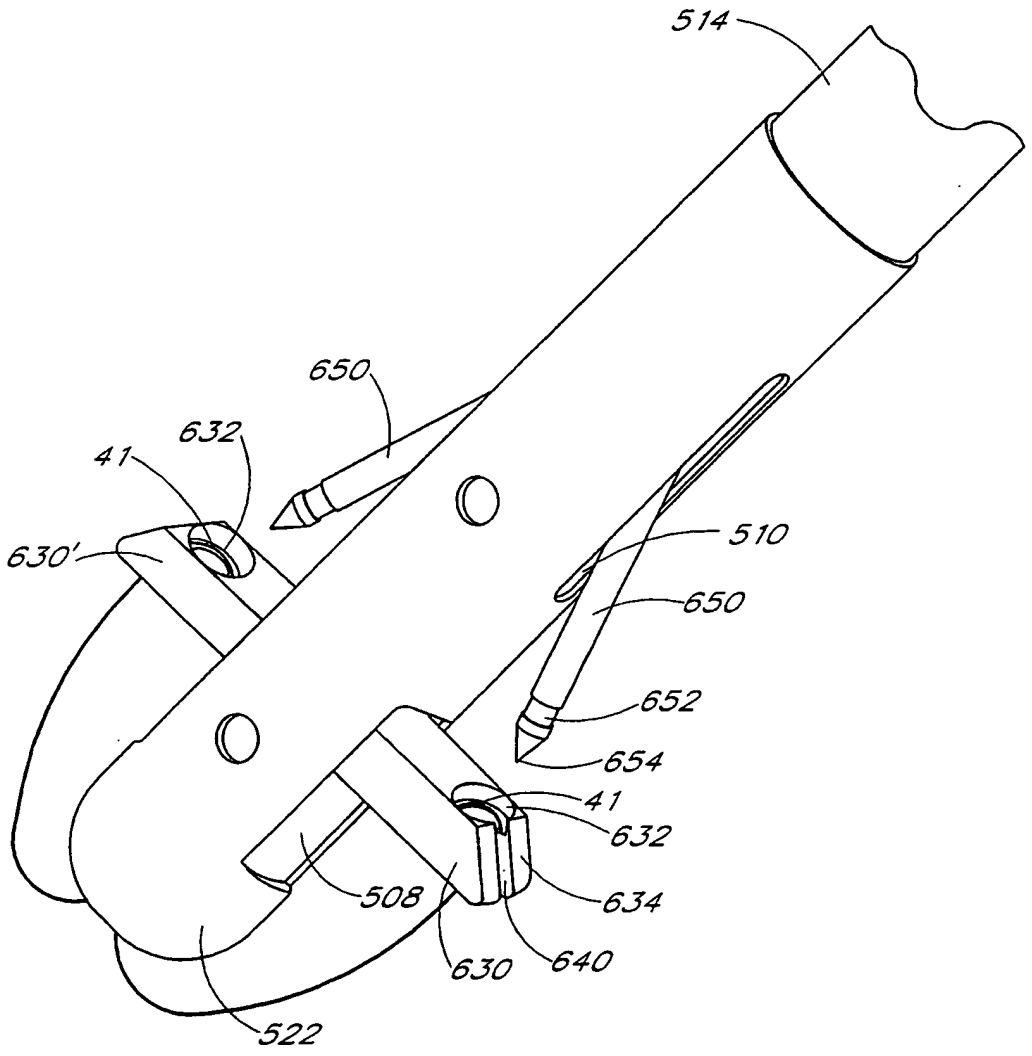

FIG. 16

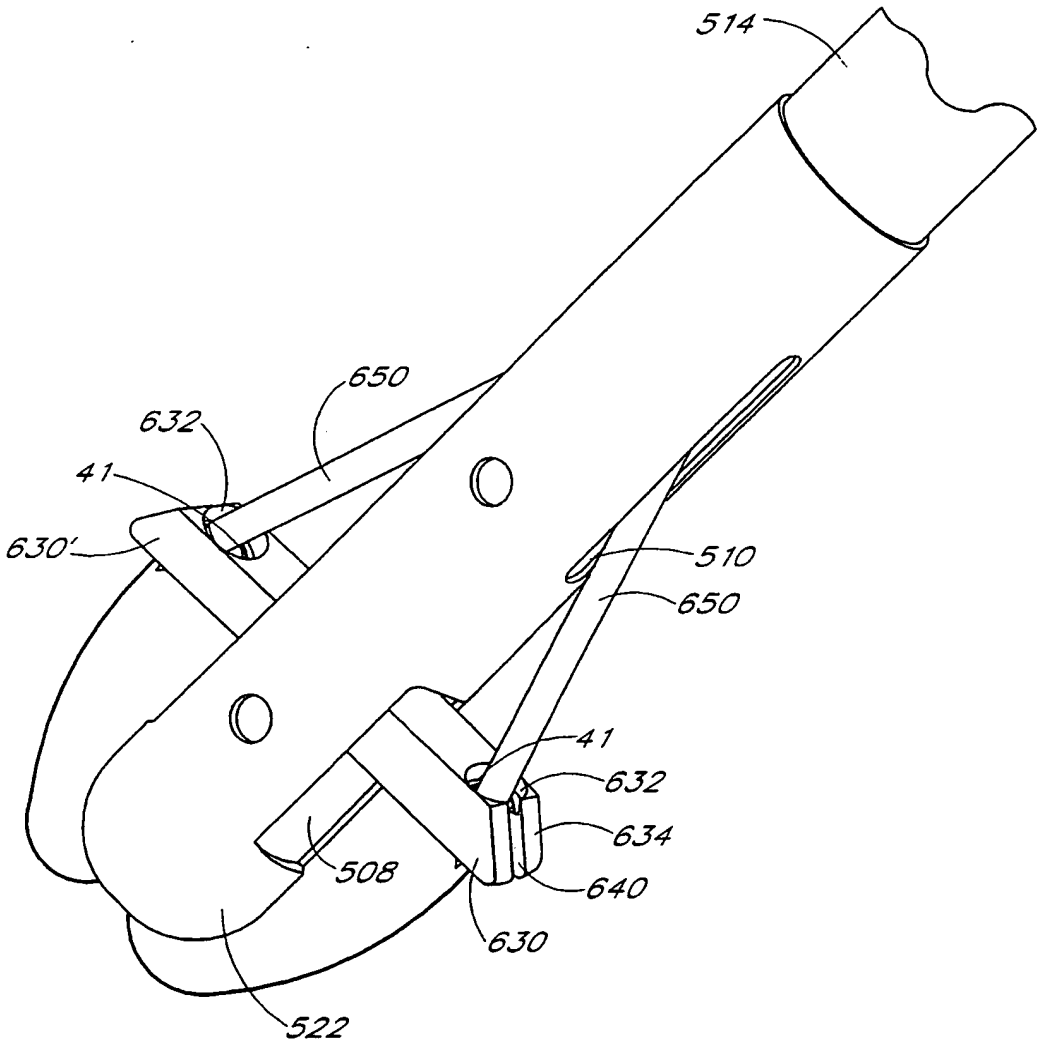

FIG. 17

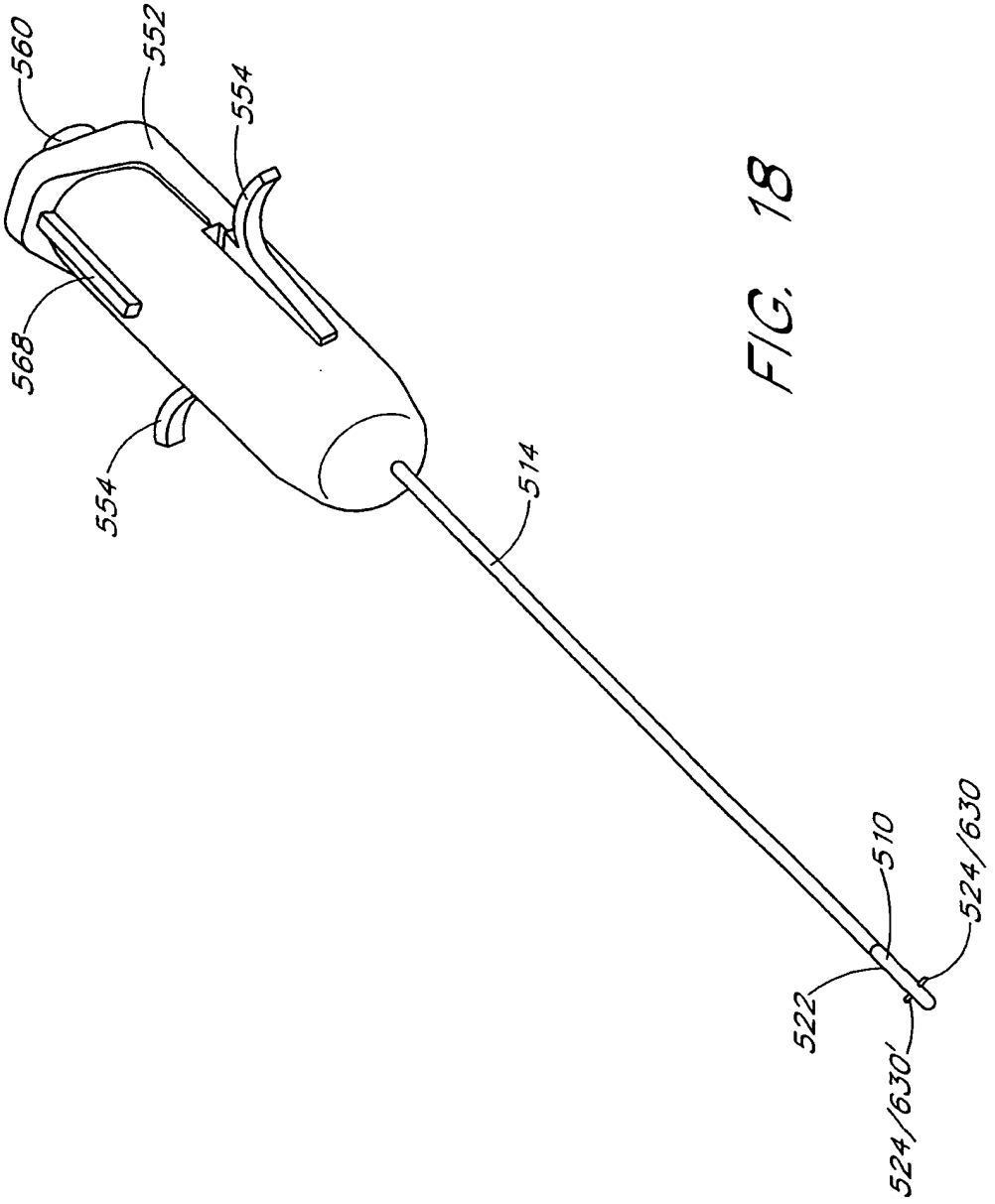

FIG. 18

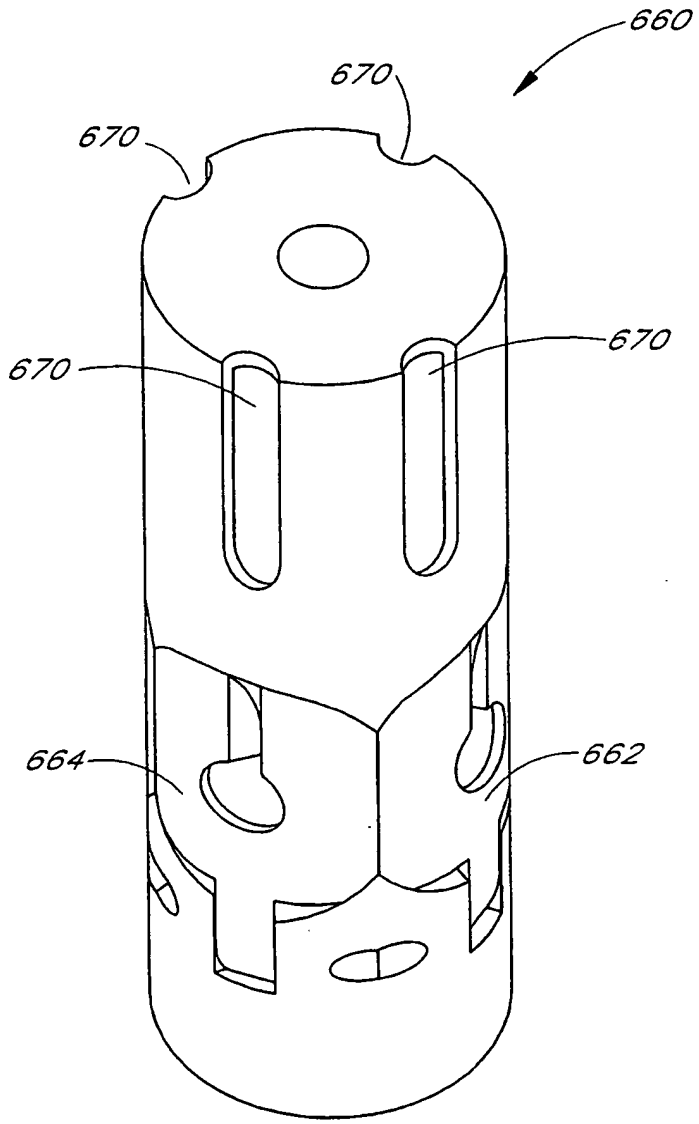

FIG. 19

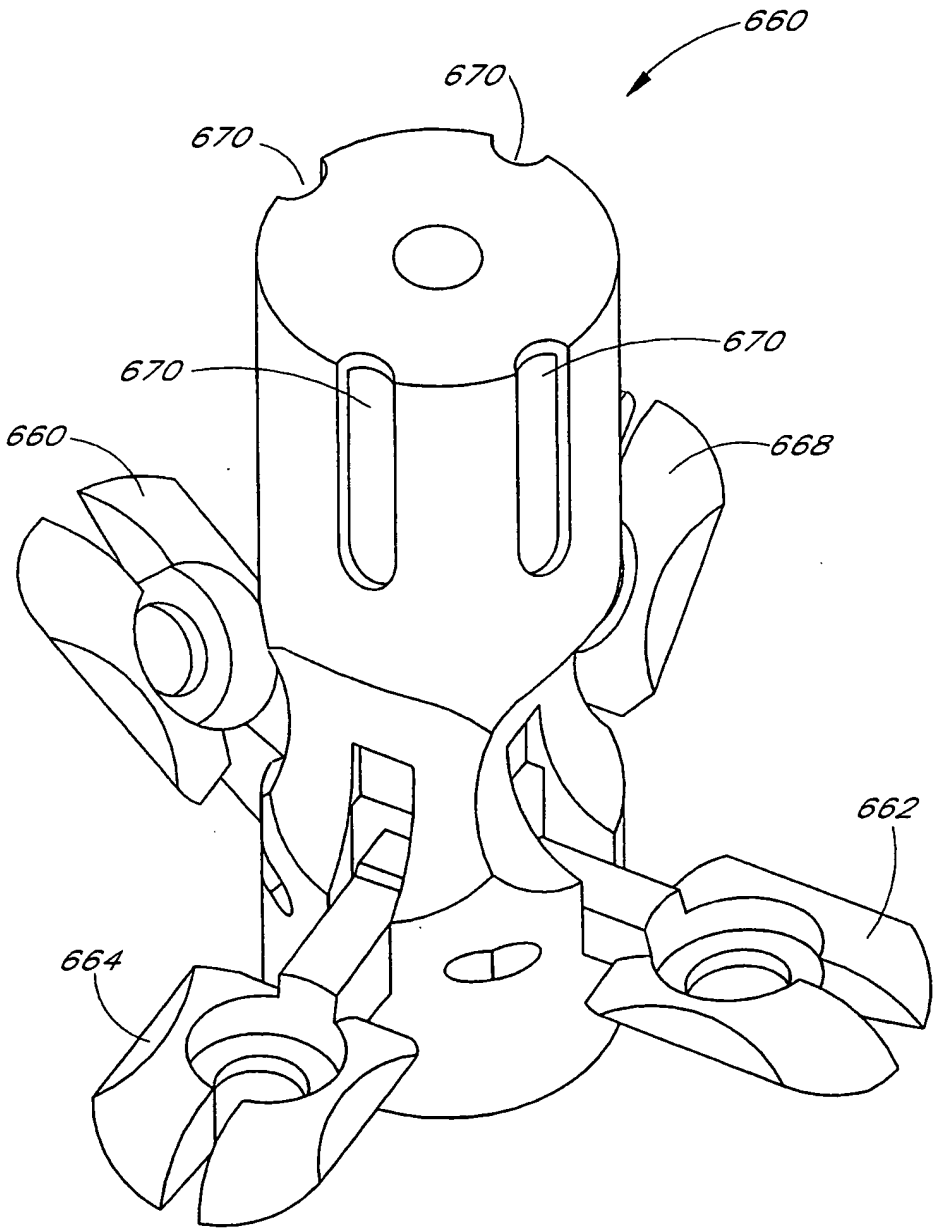

FIG. 20

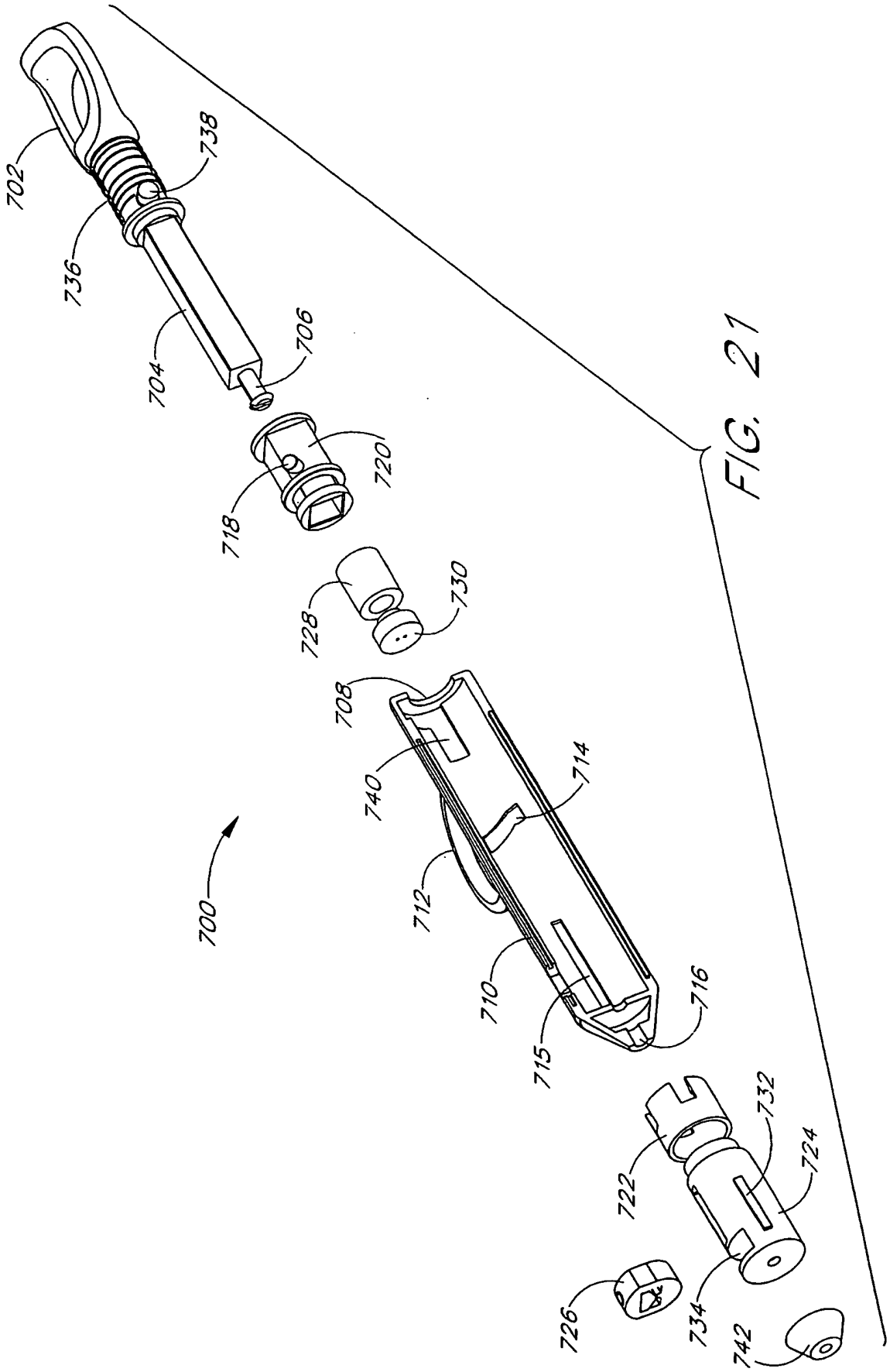
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FIG. 21

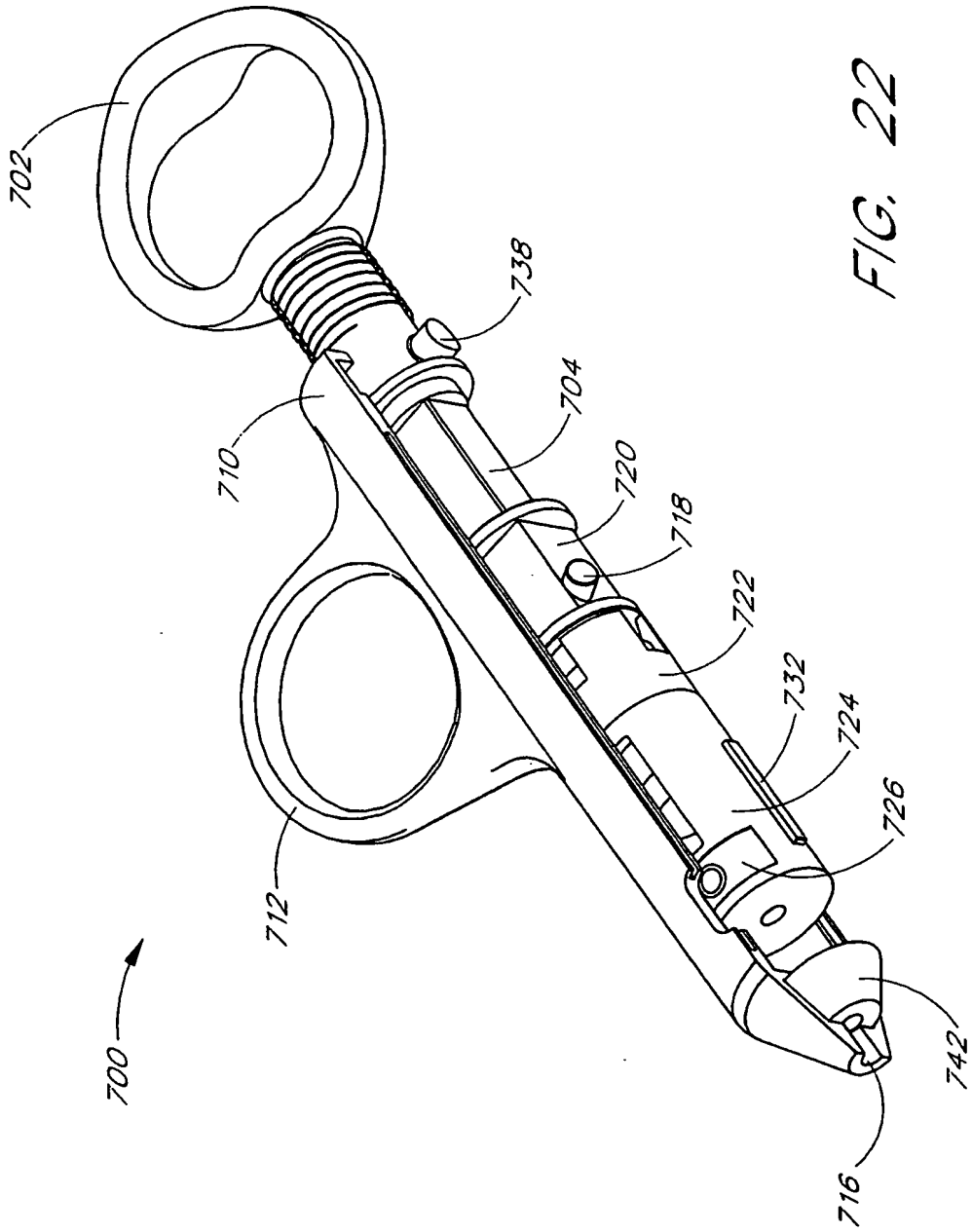

FIG. 22

INTERNATIONAL SEARCH REPORT

Intern. ...nal Application No
PCT/US 99/03904

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 07745 A (NOBLES LAI ENGINEERING INC) 6 March 1997 see page 16, line 32 - page 17, line 36	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 1999	21/06/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gérard, B

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/ 03904

B x I Observations wher certaln claims were found unsearchable (Continuati n f item 1 f first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18, 19
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern nal Application No
PCT/US 99/03904

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9707745 A	06-03-1997	AU 6858896 A	19-03-1997